

**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: 001-40498

Century Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

3675 Market Street

Philadelphia, Pennsylvania

(Address of principal executive offices)

84-2040295

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

19104

(Zip Code)

(267) 817-5790

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	IPSC	The Nasdaq Global Select Market

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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

Smaller reporting company

Non-accelerated filer

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 registrant's voting stock held by non-affiliates of the registrant was approximately \$368,259,418 as of June 30, 2022.

As of February 28, 2023, the registrant had 59,170,590 shares of Common Stock, \$0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates certain information by reference from the registrant's definitive proxy statement for the 2023 annual meeting of shareholders to be filed no later than 120 days after the end of the registrant's fiscal year ended December 31, 2022.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and the documents incorporated by reference herein contain forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Annual Report on Form 10-K or the documents incorporated by reference herein regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will,” “would,” “could,” “should,” “potential,” “seek,” “evaluate,” “pursue,” “continue,” “design,” “impact,” “affect,” “forecast,” “target,” “outlook,” “initiative,” “objective,” “designed,” “priorities,” “goal,” or the negative of such terms and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are based on assumptions and expectations that may not be realized and are inherently subject to risks, uncertainties and other factors, many of which cannot be predicted with accuracy and some of which might not even be anticipated.

The forward-looking statements in this Annual Report on Form 10-K and the documents incorporated herein by reference include, among other things, statements about:

- our ability to raise additional capital to fund our operations and continue the development of our current and future product candidates;
- the preclinical and early clinical nature of our business and our ability to successfully advance our current and future product candidates, through development activities, preclinical studies, and clinical trials;
- our ability to generate revenue from future product sales and our ability to achieve and maintain profitability;
- the accuracy of our projections and estimates regarding our expenses, capital requirements, cash utilization, and need for additional financing;
- the extent to which the COVID-19 pandemic, or any other pandemic or global health crises may impact our business, including development activities, preclinical studies, clinical trials, supply chain and labor force;
- our dependence on the success of our lead product candidate, CNTY-101;
- the novelty of our approach to immuno-oncology treatment of cancer, utilizing iPSC-derived natural killer cells, or iNK cells, and iPSC-derived T cells, or iT cells, and the challenges we will face due to the novel nature of such technology;
- the success of competing therapies that are or may become available;
- our reliance on the maintenance of our collaborative relationship with FUJIFILM Cellular Dynamics Inc., or FCDI, for access to key differentiation and reprogramming technology for the manufacturing and development of our product candidates;
- the initiation, progress, success, cost, and timing of our development activities, preclinical studies and clinical trials;
- the timing of future investigational new drug, or IND, applications and the likelihood of, and our ability to obtain and maintain, regulatory clearance of IND applications for our product candidates;

- the timing, scope and likelihood of regulatory filings and approvals, including final regulatory approval of our product candidates;
- our reliance on FCDI to be the exclusive manufacturer of certain product candidates, and our ability to manufacture our own product candidates in the future, and the timing and costs of such manufacturing activities;
- our reliance on the maintenance of our collaborative relationship with Bristol-Myers Squibb Company, or Bristol-Myers Squibb, in connection with the furtherance of our collaboration programs;
- the performance of third parties in connection with the development of our product candidates, including third parties conducting our current and future clinical trials as well as third-party suppliers and manufacturers;
- our ability to attract and retain strategic collaborators with development, regulatory, and commercialization expertise;
- the public opinion and scrutiny of cell-based immuno-oncology therapies for treating cancer and its potential impact on public perception of our company and product candidates;
- our ability to successfully commercialize our product candidates and develop sales and marketing capabilities, if our product candidates are approved;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments and approval pathways in the United States and foreign countries for our product candidates;
- the potential scope and value of our intellectual property and proprietary rights;
- our ability, and the ability of our licensors, to obtain, maintain, defend, and enforce intellectual property and proprietary rights protecting our product candidates, and our ability to develop and commercialize our product candidates without infringing, misappropriating, or otherwise violating the intellectual property or proprietary rights of third parties;
- our ability to recruit and retain key members of management and other clinical and scientific personnel;
- developments relating to our competitors and our industry;
- the volatility of capital markets and other macroeconomic factors, including due to inflationary pressures, geopolitical tensions or the outbreak of hostilities or war; and
- other risks and uncertainties, including those described or incorporated by reference under the caption “Risk factors” in this Annual Report on Form 10-K.

We have based these forward-looking statements largely on our current expectations, estimates, forecasts, and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report on Form 10-K, we cannot guarantee that the future results, levels of activity, performance,

or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section titled “Risk Factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

You should read this Annual Report on Form 10-K and the documents that we incorporate by reference herein completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

PART I

ITEM 1. BUSINESS

Overview

We are an innovative biotechnology company developing transformative allogeneic cell therapies to create products for the treatment of both solid tumor and hematological malignancies with significant unmet medical need. We have created a comprehensive allogeneic cell therapy platform that includes industry-leading induced pluripotent stem cells, or iPSCs, differentiation know-how to generate immune effector cells from iPSCs, or iPSC-derived cells, clustered regularly interspaced short palindromic repeats, or CRISPR, mediated precision gene editing that allows us to incorporate multiple transgenes and remove target genes intended to optimize cell product performance, sophisticated protein engineering capabilities to develop proprietary next generation chimeric antigen receptors, or CARs, our proprietary Allo-Evasion™ technology intended to prevent rejection of our cell products by the host immune system, and cutting edge manufacturing capabilities intended to minimize product development and supply risk. We believe that these vertically integrated capabilities will allow us to further expand our existing pipeline and develop therapeutics from iPSC-derived natural killer cells, or iNK cells, or iNK, and iPSC-derived T cells, or iT cells, or iT, that may provide enhanced clinical outcomes compared to available therapeutic options. Our vision is to become a premier fully integrated biotechnology company by developing and ultimately commercializing off-the-shelf allogeneic cell therapies that dramatically and positively transform the lives of patients suffering from life-threatening cancers. To achieve our vision, we have assembled a world-class team whose members collectively have decades of experience in cell therapy and drug development, manufacturing, and commercialization.

The field of cell therapy is rapidly evolving, with autologous and allogeneic technologies demonstrating the strong potential of this therapeutic modality. We believe that our industry leading, end-to-end iPSC-derived allogeneic cell therapy platform will allow us to overcome technical and biological limitations of other donor-derived cell therapies. The unlimited replication capacity of iPSCs allows us to incorporate multiple genetic modifications at precise sites, or loci, in the genome of iPSCs that are designed to improve cell function using a CRISPR-mediated approach targeting a DNA repair pathway called homology directed repair, or HDR. The precision of our CRISPR-HDR gene editing technology and clonal selection eliminates random integration events and allows more controlled expression of transgenes of interest compared to other gene editing methodologies. The self-renewal capacity of iPSCs also enables the generation of master cell banks derived from single genetically engineered clones thus allowing the implementation of cost-efficient manufacturing of drug product that can be made available on demand at any clinical site. We have assembled a unique and powerful combination of technologies that bring together a preeminent iPSC-derived allogeneic cell therapy platform with highly advanced cell engineering and manufacturing capabilities. We believe this unique combination puts us in a position to change the oncology treatment paradigm and market.

The key elements of our approach include:

Our efficient precision gene editing technology:

We have developed highly efficient gene engineering processes to generate our product candidates. Our first product candidate, CNTY-101, has six CRISPR-mediated homologous recombination and repair edits, and we plan to incorporate additional edits in our future product candidates. We are currently using the CRISPR-MAD7 nuclease to enable precise editing of the iPSC genome, and have developed proprietary applications of the CRISPR-MAD7 technology to genetically modify iPSCs by simultaneously removing target genes or adding transgenes (which is commonly known as knocking-out and knocking-in, respectively) of interest at precise genetic loci. Our approach is designed to preserve genome integrity and achieves more predictable and consistent transgene expression as compared to approaches driven by viruses or transposable segments called transposons, which result in varied gene copy number and random integration events that risk mutations, namely insertional mutagenesis.

Our proprietary Allo-Evasion™ technology:

We are leveraging our Allo-Evasion™ technology to design cells capable of evading identification and destruction by the host (patient) immune system. We believe this technology may permit dosing in patients with limited or no immune preconditioning regimens. The reduction in allogeneic immune-reactivity enabled by our use of this technology, which is designed to prevent rejection by the patient's immune system may allow repeat dosing of our CAR-modified cell therapies, and sustain therapeutic efficacy over a long period of time.

CAR and protein engineering:

CAR design is a critical component of innovative cell therapy product candidates. We assembled a team of scientists with deep protein engineering expertise and invested in the use of the variable domain of the heavy chain antibody, or VHH binders. We believe that this antibody platform investment to develop world-class CAR engineering capabilities will allow us to create multi-specific CAR constructs targeting more than one tumor antigen. We believe that targeting multiple antigens on tumor cells will help address tumor heterogeneity and antigen loss, which are frequently observed in tumor cells. We have created a proprietary synthetic library of humanized VHH binders to enable in-house binder screens and multiple campaigns against several tumor antigens are ongoing to generate the CAR constructs for future product candidates.

Common engineered iPSC progenitor accelerates new product candidate generation:

With other cell therapy platforms generated from cells with limited replicative capacity, the creation of a new product candidate requires starting over with each of the gene engineering steps having to be incorporated into the product. This is not only time and resource intensive; it also makes it more difficult to predict functionality and safety profile based upon products that may have been clinically tested in earlier programs. In contrast, all of our iPSC- derived product candidates include a set of shared core features intended to increase their functionality, safety, and persistence. We integrate these core features into common engineered iPSC progenitors, which have several advantages:

Significant acceleration of new product candidate generation.

Multiple product candidates are generated by engineering additional features, such as adding different CARs to the common progenitor to create new product candidates for different tumor indications. With this approach, we do not need to re-engineer common functionalities every time we generate a new product candidate.

Robust manufacturing processes for multiple product candidates.

Since the starting iPSC line is the same for multiple product candidates, our manufacturing processes are predictable and robust.

Predictability of product candidate functionality, safety profile, and persistence.

Because multiple clinical candidates are derived from the same engineered iPSC line, the lessons learned from one product candidate can be leveraged across multiple product candidates, which facilitates further product development. For instance, we believe the allo-reactivity of products derived from the same common engineered iPSC progenitor should be very similar.

We received a study may proceed notification from the U.S. Food and Drug Administration, or the FDA, for our lead product candidate CNTY-101, a CAR-iNK product candidate targeting CD19 for lymphoma, in August 2022. We initiated the Phase 1 ELiPSE-1 trial in CD19+ B-cell lymphomas and began dosing patients in February 2023. Our second product candidate, CNTY-102, is a bi-specific CD19 + CD22 CAR - iT product

candidate targeting lymphoma. Our newest product candidate, CNTY-107, is a Nectin-4 CAR - iT targeted product candidate for Nectin-4 positive solid tumors.

In January 2023, we announced a strategic internal portfolio prioritization through which, among other discovery efforts, CNTY-103, a CAR-iNK product targeting CD133 and a discovery program for hematological malignancies, were de-prioritized, allowing us to further prioritize our CNTY-102 and CNTY-107 product candidates, which we believe have a higher probability of technical success and greater market potential. As a result of the operational restructuring, lab operations in Seattle and Hamilton have been closed and research activities have been consolidated in Philadelphia.

In January 2022, we entered into a strategic collaboration with Bristol-Myers Squibb Company, or Bristol-Myers Squibb, to develop and commercialize up to four iNK or iT programs for hematological malignancies and solid tumors. The collaboration includes our fourth candidate, CNTY-104, a multi-specific collaboration program targeting acute myeloid leukemia, or AML, and CNTY-106, a multi-specific collaboration program for multiple myeloma. As there are disease settings which will favor iNK or iT products, we are actively investigating both iNK and iT cell platforms for CNTY-104 and CNTY-106, as either may have preferential clinical features.

We are also advancing an earlier discovery stage pipeline with novel CARs and binders against multiple solid and hematological tumor targets using our iNK and iT cell therapy platforms. We believe that the therapeutics we discover and develop, if approved, will have a significant impact on the quality of life of patients suffering from devastating malignancies. Our approach to developing therapies for life-threatening cancers of highly unmet medical need potentially presents an opportunity to efficiently advance our product candidates through clinical development, regulatory approval and ultimately to commercialization.

Our collaboration with FUJIFILM Cellular Dynamics Inc., or FCDI, provides us with licenses to certain premier iPSC technologies, patents and know-how, which gave us our initial start and enabled us to accelerate generation of our first-generation product candidates and development of our manufacturing processes. We have built and expanded on this foundation with our own resources, applying our own gene editing, protein engineering, process development, and manufacturing expertise to develop our novel product candidates and platforms for which we are developing our own intellectual property. We retain exclusive commercialization rights in the United States and other major commercial markets for our product candidates developed pursuant to our collaboration with FCDI.

Our pipeline

We are assembling a portfolio of allogeneic iNK and iT cell therapy product candidates across solid tumor and hematological malignancies. This pipeline is comprised of cell therapies that will address diseases where we believe current therapies are inadequate. All product candidates incorporate our proprietary Allo-Evasion™ technology to avoid host rejection and potentially increase the durability of clinical responses. We received a safe to proceed notification from the FDA for our first product candidate, CNTY-101 for the treatment of CD19+ B-cell malignancies in August 2022. In February 2023, we announced that we started dosing patients in the first-in-human Phase 1 ELiPSE-1 trial evaluating CNTY-101 in relapsed or refractory CD19 positive B-cell lymphomas.

Our second product candidate, CNTY-102, is designed to further improve B-cell malignancy treatment by simultaneously targeting CD19 and a second antigen. Our newest product candidate, CNTY-107 is a Nectin-4 targeted product for Nectin-4+ tumors. In collaboration with Bristol Myers Squibb, we are developing CNTY-104 to treat AML. We are also developing CNTY-106 in collaboration with Bristol-Myers Squibb for multiple myeloma.

Our development programs consist of the product candidates illustrated in the pipeline chart below:

Product	iPSC Platform	Targets	Indications	Discovery	Preclinical	Clinical			Collaborator
						P1	P2	P3	
CNTY-101	iNK	CD19	B-Cell Malignancies						
CNTY-102	iT	CD19 + CD22	B-Cell Malignancies						
CNTY-107	iT	Nectin-4	Solid Tumors						
Programs in Collaboration									
CNTY-104	iNK/iT	Multi-specific	Acute Myeloid Leukemia						Bristol Myers Squibb
CNTY-106	iNK/iT	Multi-specific	Multiple Myeloma						Bristol Myers Squibb
Research Programs									
Discovery	iNK/iT	TBD	Hematological / Solid Tumors						

Solid Tumors Hematologic Tumors

- (1) We are party to an option agreement with Bayer HealthCare LLC, or Bayer, pursuant to which Bayer was granted certain bidding rights relating to the potential transfer of rights with respect to certain product candidates being researched and developed by us which are comprised of iNK cells, macrophages or dendritic cells, and any other product candidate comprised of iNK cells that we develop in the future. CNTY-101 is no longer included in the agreement. Bayer's rights under the option agreement are subject to important limitations. See “—Licensing, partnership and collaboration— Bayer HealthCare LLC—Option Agreement” for more information.
- (2) We entered a collaboration with Bristol-Myers Squibb to develop and commercialize up to four iNK or iT product candidates, including CNTY-104 and CNTY-106. See – Licensing, partnership and collaboration – Bristol-Myers Squibb for more information.

CNTY-101: Our CAR-iNK product candidate targeting CD19 for relapsed, refractory B-cell lymphoma.

Our lead product candidate, CNTY-101, is an allogeneic, iPSC-derived CAR-iNK cell therapy that has been engineered to express CD19 CAR, soluble IL-15, an EGFR safety switch, and also contains gene edits needed to incorporate Allo-Evasion™ technology. We are currently dosing patients in the Phase 1 trial for CNTY-101, ELiPSE-1.

CNTY-102: Our CAR-iT product candidate targeting CD19 + CD22 for relapsed, refractory B-cell lymphoma and other B-cell malignancies.

The Company has selected targets for CNTY-102, a CAR-iT product candidate, against CD19 and CD22 for relapsed, refractory B-cell lymphoma and other B-cell malignancies. CNTY-102 will simultaneously target CD19 and CD22, intended to increase depth and durability of response by eliminating the effect of CD19 antigen loss that has been observed as a factor limiting treatment durability, as well as targeting CD22, an independently regulated, ubiquitous and validated B-cell target. We have elected to develop CNTY-102 on our gamma delta iT platform.

CNTY-107: CAR- iT product candidate for the treatment of solid tumors expressing Nectin-4

CNTY-107 is an iPSC-derived Nectin-4 CAR gamma delta T-cell therapy product candidate that will be engineered with multiple features to provide several mechanisms for tumor killing. The product candidate will include core Allo-Evasion™ edits and other features designed to provide cytokine support, enhance tumor cell killing and cell fitness.

CNTY-104: Our CAR-iNK or CAR-iT multi-specific collaboration program for acute myeloid leukemia.

CNTY-104 will utilize our multi-specific iNK or iT cells for the treatment of AML, which we intend to develop in collaboration with Bristol-Myers Squibb. We will evaluate both the iNK and iT cell therapy platforms and choose the one likely to provide the best therapeutic index in the clinic.

CNTY-106: Our CAR-iNK or CAR-iT multispecific collaboration program for multiple myeloma.

CNTY-106 will utilize our multi-specific iNK or iT cells for the treatment of multiple myeloma, which we intend to develop in collaboration with Bristol-Myers Squibb. We will evaluate both the iNK and iT cell therapy platforms and select the one that we believe will be most likely to provide the best therapeutic index in the clinic.

Discovery platform.

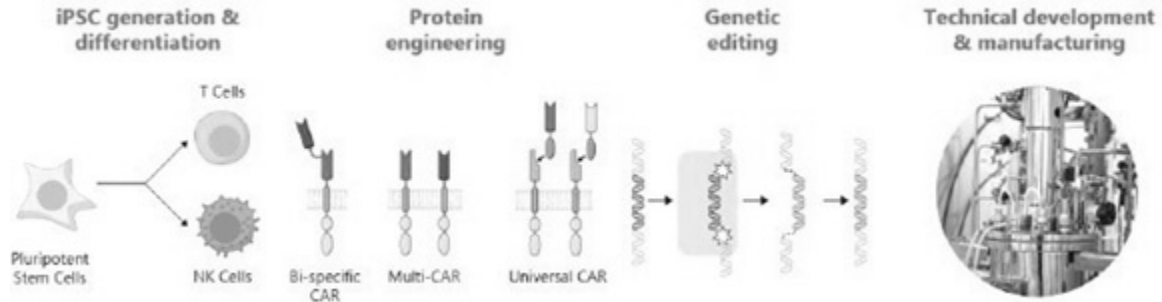
In addition to our named programs, we are actively engaged in a number of earlier stage discovery programs where we believe our iPSC-derived allogeneic cell therapy platform may provide differentiated therapeutic benefits. These discovery stage initiatives are focused on several solid tumor indications including renal cell carcinoma and other indications. For these and other indications, we plan to use multispecific CARs and explore the use of both iNK and iT cells to identify the best cell platform to build the product candidate. We continue to advance our gamma delta and alpha beta iT cell platforms for our future T cell based candidates.

Our use of iPSCs provides us with a differentiated advantage in product development and manufacturing

The majority of allogeneic approaches currently in development use differentiated T cells or NK cells derived from the peripheral blood of healthy donors. Although the use of allogeneic cells in the manufacture of CAR-based T cell or NK cell therapies offers significant advantages, the use of donor cells in the production of allogeneic cell therapies has significant limitations. For example, the number of doses that can be produced from a single donation of blood is limited, such that multiple donations will be needed over the lifetime of a product. Therefore, genetic modifications must be performed in their entirety following each donation. Furthermore, all blood, even from the same donor collected at different times, has some degree of variability and, as a result, product comparability from donation to donation must be demonstrated. In addition, the number of edits that can be introduced into the genome of T cells or NK cells is severely limited, as each engineering step requires cells to replicate. Excessive expansion cycles often result in cell exhaustion, with the engineered lymphocytes (white blood cells) expressing checkpoint molecules, often accompanied by a loss of functionality. As a consequence, the engineering process for these donor-derived cell therapies requires a careful balancing between the number of replication cycles achievable and the generation of fully functional cells resulting in significant limitations.

We believe our engineered, iPSC-derived allogeneic cell therapy platforms can overcome many of the challenges inherent to cell therapy, provide a significant advantage over existing cell therapy technologies. We are focused on developing novel therapeutics designed to address many of the significant unmet medical needs in cancer treatment.

Core characteristics of our iPSC-derived allogeneic cell therapy platforms

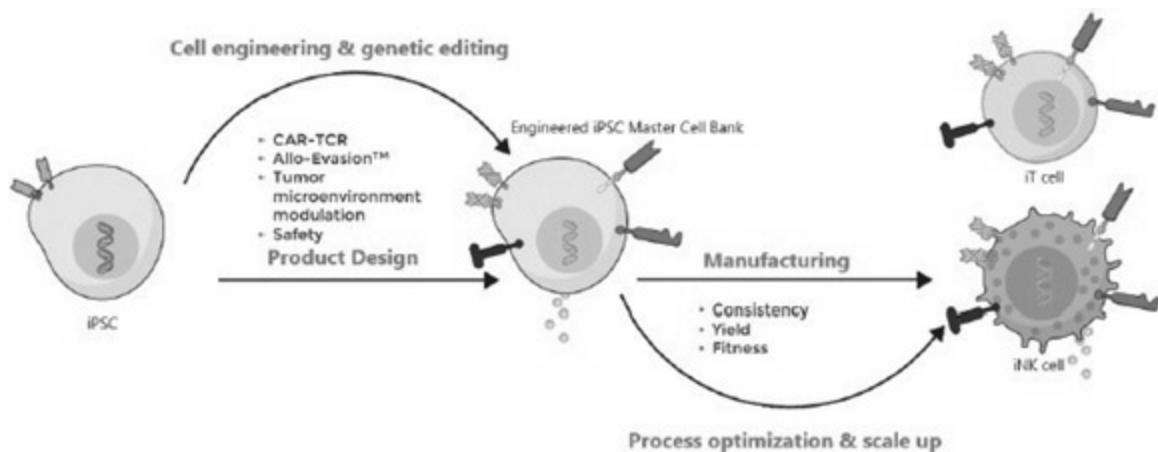


Our iPSC-derived allogeneic cells differentiate our therapeutic development approach

The source cells used in the manufacture of our allogeneic cell therapy candidates are iPSCs. An iPSC is a type of stem cell that can be generated directly from a somatic cell. A somatic cell is a cell that has become functionally differentiated, or specialized, such as a blood cell, skin cell or bone cell. iPSC-derived cell products offer significant technical and manufacturing advantages. These cells have unlimited replication capacity and can act as a progenitor cell for other cell types, including the different types of immune cells. iPSCs share similar biological properties with embryonic stem cells, such as morphology, patterns of gene and protein expression, and growth properties including mitotic activity and doubling time. Our in-licensed iPSC technology allows us to reprogram differentiated cells into iPSCs and to somatic the iPSCs to generate different immune cell types including iNK cells and iT cells.

We believe the use of iPSCs will enable us to manufacture cell therapies of increased consistency, in a shorter period of time, at scale and at reduced cost compared to donor-derived NK or T cell therapies. Unlike these donor-derived cell therapies where all the engineering steps are performed using differentiated cells, all of our engineering procedures are performed on iPSCs. We believe that using iPSCs as a starting point for our cell therapies will allow us to produce our allogeneic cell therapies in an efficient and consistent manner. iPSCs are more amenable to multiple genetic manipulations than differentiated lymphocytes and are capable of maintaining their viability through numerous expansion rounds. We select specific single cell clones from bulk engineered cell product, which we characterize to include specified edits and ensure the absence of off-target genomic alterations. A single cell clone is used to construct a master cell bank capable of providing a sufficient number of doses for the life of a product due to the unlimited replicative capacity of iPSCs.

Our use of iPSCs provide us with differentiated advantages in product development and manufacturing



Our strategy

Our vision is to be a leader in the treatment of both solid tumor and hematological malignancies that address unmet medical needs by developing innovative allogeneic cell therapy products derived from our proprietary technologies. We are initially focused on advancing the research, clinical development and commercialization of tumor-targeted iNK and iT cell therapeutics. We believe that our iPSC-derived allogeneic cell therapy platforms have the potential to overcome the limitations of existing therapies, lower manufacturing costs and improve patient outcomes. To deliver on our mission, we intend to:

- **Build a leading cell therapy company leveraging our comprehensive iPSC-derived allogeneic cell therapy platforms designed to overcome the limitations of existing cancer therapies.** We have created comprehensive allogeneic cell therapy platforms that include industry-leading iPSC differentiation know-how, CRISPR-mediated precision gene editing, sophisticated protein engineering capabilities, proprietary Allo-EvasionTM technology, and cutting-edge manufacturing capabilities. We believe the incorporation of these elements into our platforms affords us numerous advantages over autologous and donor-derived differentiated T, NK and other cell therapies, and may eliminate many of the challenges inherent in these other cell therapy modalities.
- **Maximize the potential to treat a broad range of cancers by exploiting the distinct biologies of both NK and T cells. We are initially developing our CAR-iNK and CAR-iT cell therapy platforms for multiple indications including lymphoma, Nectin-4 positive tumors, acute myeloid leukemia, multiple myeloma and other solid tumor and hematological malignancies.** We anticipate each platform will have a distinct biology that influences its function, and accordingly, the disease settings in which it is best suited for development. We view this dual development strategy as an opportunity to maximize the potential benefits of each platform and its associated immune cell. In the future, we may develop regimens that simultaneously incorporate both CAR-iNK and CAR-iT cells in the treatment of individual patients.
- **Leverage our Allo-EvasionTM technology across our product platform to avoid host rejection and enable repeat dosing.** Central to the potential clinical performance of our iPSC-derived cell therapies is our novel and proprietary Allo-EvasionTM technology, which we intend to implement across our entire product platform. This proprietary technology allows us to engineer cells designed to avoid recognition and rejection by the host immune system. Furthermore, it enables repeat dosing, which we believe will enable us to immediately reinforce the immunological line of defense as cells dosed previously succumb to immune exhaustion and provide our cell therapies the benefit of enhanced durability and persistence. We believe this may reduce or possibly eliminate the need for immune preconditioning regimens, and enhance the recruitment of host immune cells to participate in the anti-tumor response. We believe these advantages could enable the implementation of more flexible and effective dosing protocols for our off-the-shelf product candidates, which we anticipate will increase physician and patient access.
- **Exploit serial gene editing of iPSCs to create product candidates with enhanced functionalities and fit for purpose product characteristics.** We utilize CRISPR-mediated precision gene editing that allows us to incorporate multiple transgenes and knock-outs to achieve precise genetic modifications at defined locations in the iPSC genome. Our lead clinical product candidate, CNTY-101, incorporates six gene edits, which we believe are essential attributes necessary for meaningful clinical performance, including a CAR to mediate tumor recognition and killing, features to evade immune rejection and a safety switch to enable product elimination if ever necessary. We believe this initial set of gene edits will form the foundation for follow-on product candidate development. Additionally, we believe our investment in our gene editing technology will allow us to expand upon our current capabilities and integrate further fit for purpose gene edits intended to enhance clinical performance of our future product candidates.

- **Leverage our own manufacturing infrastructure, product and process understanding, and scale-up technologies to minimize manufacturing risk.** We are strategically investing in manufacturing across all aspects of the value chain to become leaders in the industry. We have built internal manufacturing facilities, including our Branchburg, New Jersey Current Good Manufacturing Practices, or cGMP, plant, that we believe will enable us to learn and iterate more rapidly and increase control of development timelines for expedited development of high-quality product candidates. We are in the process of tech transferring the first product into our cGMP facility for the purpose of producing and releasing it, as well as future products, from this facility for clinical trials. We will continue to invest in process and analytical development capabilities and closely study our cell process parameters that affect product quality. Furthermore, we intend to establish expertise in scale-up technologies designed to enable optimal manufacturing scale, which we believe will reduce cost of goods and improve patient access.

Background

The role of NK cells and T cells in the human immune system

The human immune system is comprised of two integrated systems, the innate immune system and the adaptive immune system. The innate immune system involves an immediate, non-specific response to recognize and protect against foreign pathogens based on broadly conserved pathogen associated molecular patterns and generally lacks pathogen or disease-specific immune memory.

Innate immune system—NK Cells

Cytotoxic NK cells are part of the front-line innate immune response, and in this capacity, monitor the body for signs of pathogens or signals of disease. NK cells have the unique ability to selectively identify and destroy abnormal cells through multiple direct and indirect mechanisms while leaving normal healthy cells unharmed. These mechanisms include (i) direct innate killing by binding to stress ligands expressed by diseased or dysfunctional cells and releasing toxic granules and perforins, (ii) indirect killing by producing and releasing proinflammatory cytokines that play a pivotal role in orchestrating the adaptive immune response, and (iii) antibody-mediated targeted killing by binding to cells targeted for elimination through a process known as antibody-dependent cellular cytotoxicity.

Adaptive immune system—T Cells

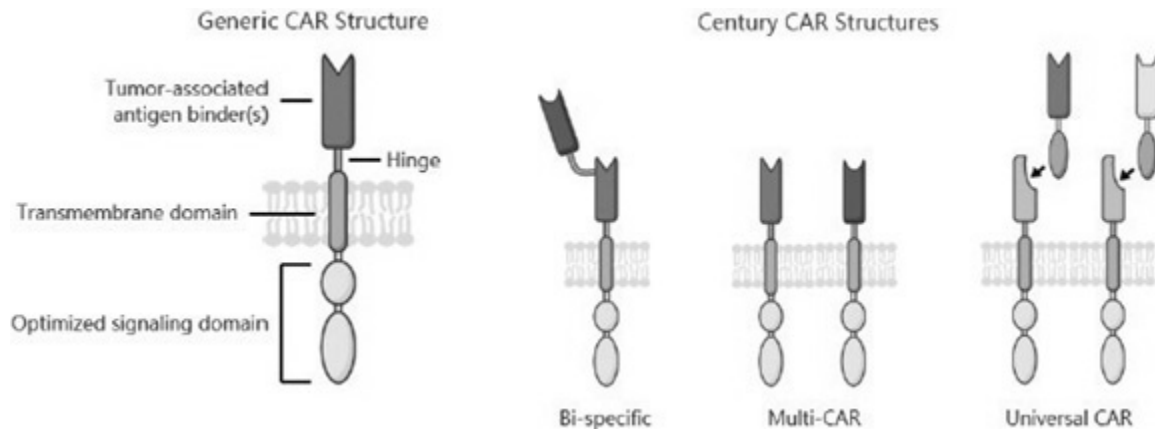
The adaptive immune system is characterized by antigen-specific immune responses mediated by T and B cells. T cells are distinguished from other immune system cells by the presence of a T cell receptor, or TCR, on their surface. TCRs are activated through engagement with antigens on the major histocompatibility complex, or MHC, of cells. In humans, these antigens are known as human leukocyte antigens, or HLAs. Upon antigen recognition, CD8 T cells, also referred to as cytotoxic lymphocytes, or CTLs, bind to the MHC-antigen complex, become activated and destroy the targeted cell. The adaptive immune responses require several days to develop because T and B cells need to undergo clonal expansion before they can mount an immune response. The innate and adaptive immune systems also differ on the longevity of the immune response. After elimination of the pathogen, T and B cells can persist for decades as memory cells and quickly respond to new challenges by the same pathogen. We seek to take advantage of the unique properties of T cells and their proven anti-cancer activity to engineer iPSC-derived T cell products.

Cellular immunotherapy and its use in the treatment of cancer

Cellular immunotherapy is a type of immunotherapy that focuses on modulating or enhancing the activity of different lymphocytes, in particular CTLs and NK cells, to treat cancer. The cells are typically engineered with receptors that redirect them to recognize and destroy tumor cells. A frequently used approach for cellular immunotherapy involves CARs on the surface of a lymphocyte that enable the CTL or NK cell to recognize specific antigens that are present on the surface of tumor cells.

At one end of the CAR is single or multiple binding domains that engage one or more target antigens. These binding domains are exposed to the outside of the engineered lymphocyte, where they can recognize the target antigen or antigens. To enable the engineering of multi-specific CARs, we use camelid VHH antibodies.

Our use of camelid VHH antibodies enables our design of multi-specific binding domains

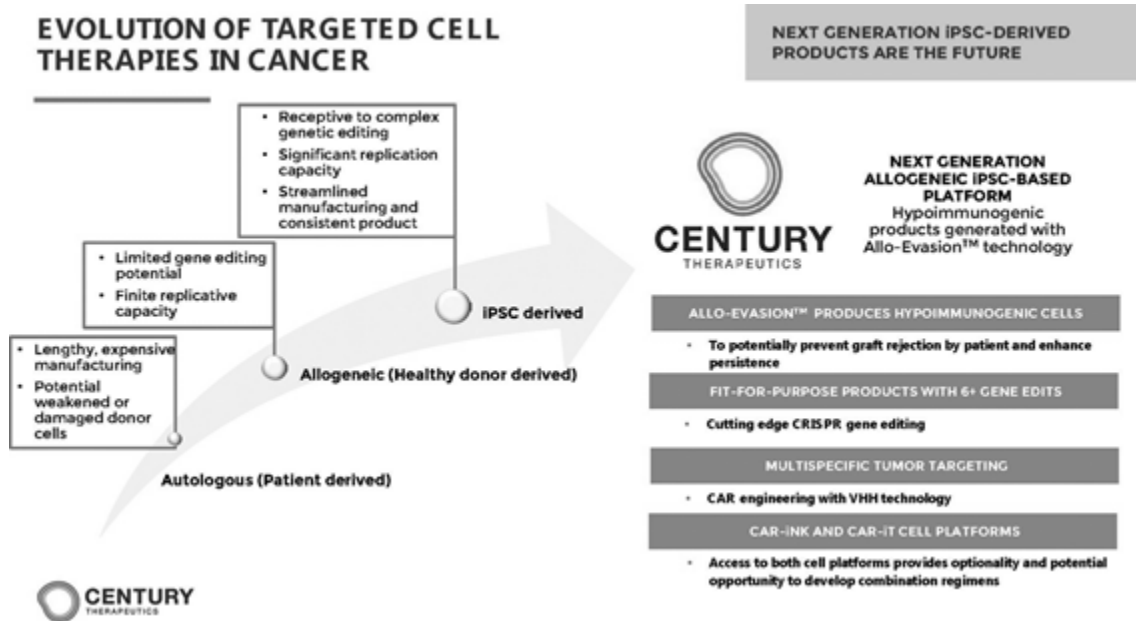


As illustrated above, our CAR constructs incorporate VHHs. VHH domains are derived from a camelid antibody, a type of antibody found in camels, llamas and sharks, that consists of a heavy chain only with one variable region. This structure gives us greater design flexibility, including the use of concatemers that target multiple epitopes on the same antigen (biparatopic CARs) or multiple tumor antigens (bi- or tri-specific CARs).

Advancements in cell therapy approaches have enhanced treatment alternatives for patients

Cell therapy has built on the success of already approved autologous CAR-T cell therapies. Allogeneic therapy, which uses lymphocytes donated by a healthy donor as the starting material, is designed to overcome several limitations inherent in the autologous approach. We believe the use of iPSC-derived cells further expands the therapeutic potential of cell therapy beyond those that utilize healthy donor-derived NK or T cells.

Evolution of targeted cell therapies in cancer



Advantages of iPSC vs. donor-derived approaches

An iPSC is a type of stem cell that can be generated directly from a functionally differentiated somatic cell such as a blood cell, skin cell or bone cell. iPSC-derived cell products offer what we believe are significant technical and manufacturing advantages compared to both autologous and other allogeneic approaches. iPSC cells can propagate indefinitely and can act as a progenitor cell for other cell types, including the different types of immune cells. Our iPSC technology allows us to reprogram differentiated cells to become iPSCs and to then differentiate the iPSCs to generate different immune cell types including NK cells and T cells. We believe some of the advantages offered by iPSCs are:

Receptive to complex genetic editing.

We believe that iPSCs are far more amenable to multiple genetic manipulations than donor-derived NK cells and T cells because iPSC cells can undergo multiple rounds of replication without loss of functionality. In contrast, differentiated cells used in donor derived allogeneic approaches are limited to just a few genetic edits, which can impact their overall functionality. The number of edits that can be introduced into the genome of differentiated NK cells or T cells is limited because each engineering step requires cells to replicate and too many expansion cycles often result in cell exhaustion and loss of functionality.

Significant replication capacity.

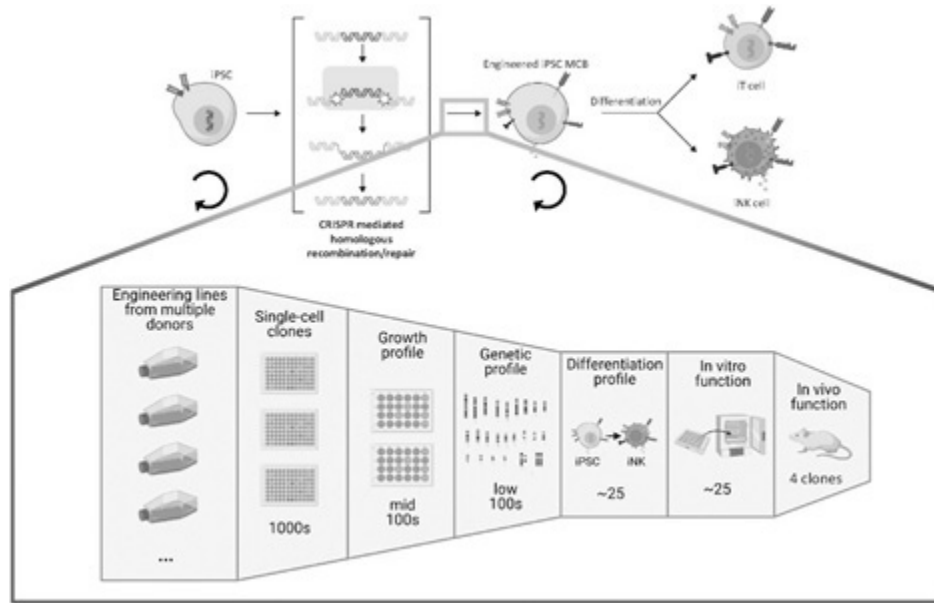
iPSCs are derived from single cell clones, which are used to construct a master cell bank capable of providing a sufficient number of doses for the life of a product due to the unlimited replicative capacity of iPSCs.

Streamlined manufacturing and consistent product.

The use of a single master cell bank allows iPSC-derived products to be produced with greater consistency, at the greatest possible scale and at reduced cost compared to donor-derived NK cells or T cells.

We believe that iPSC-derived cell therapies provide meaningful advantages over other modalities and have the potential to change the oncology treatment paradigm.

Stages of iPSC gene editing, characterization, and clonal selection



Stages of iPSC gene editing, characterization, and clonal selection prior to the generation of the engineered iPSC master cell bank (MCB). Genetic engineering of our product candidates occurs exclusively at the iPSC stage, where the cells have unlimited replicative capacity and pluripotency. In the above figure, we highlight the multiple steps required for selection of the final CNTY-101 product candidate. Gene edited iPSCs from multiple donors were enriched for having the introduced transgenes and knockouts and subsequently cloned at the single cell level. Uniform expression of the transgenes and knockouts was confirmed, and clones were evaluated for their growth potential, genetic profile, differentiation potential into iNK cells, in vitro functionality, and in vivo performance (tumor growth inhibition, persistence and toxicity).

Our rationale for developing both iNK and iT allogeneic cell therapy platforms

We are initially focusing on two immune effector cell platforms, CAR-iNK and CAR-iT. We anticipate each platform will have a distinct biology that influences its function, and accordingly, the disease settings in which it is best suited for development. We view this dual development strategy as an opportunity to maximize the potential benefits of each platform and its associated immune cell. In the future, we may develop therapies that simultaneously incorporate both CAR-iNK and CAR-iT cells in the treatment of individual patients. We believe that gene engineering and control over differentiation during manufacturing may mitigate some of the liabilities of a given cell type while preserving the most desirable features. Examples of this include the potential reduction of the risk of graft-versus-host disease, or GvHD, in iT cells through the use of TCRs that are not expected to cause GvHD, which we refer to herein as Trusted

TCRs, or the potential extension of cell persistence of NK cells through the addition of cytokine signaling to promote survival. Finally, there are also clinical settings in which a putative shortcoming inherent to one cell type (e.g., short persistence of NK cells) might confer an advantage.

Ultimately, the development of both platforms enables a unique opportunity to merge the intrinsic biology of these lymphocyte subsets with desirable engineering attributes to tailor therapies best suited for the clinical path being pursued.

Development of CAR-NK and CAR-T platforms: distinct biology influences disease-specific applications

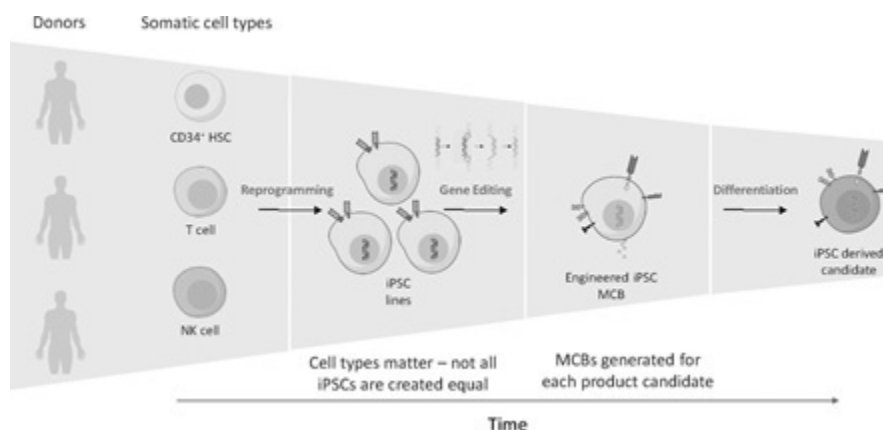
NK vs T CELL BIOLOGY	
Proliferative capacity	T cell >> NK cell
Persistence/memory	T cell >> NK cell
Pharmacokinetics	Cmax and AUC after single dose: T cells > NK cells
Trafficking	NK cell: lympho-hematopoietic compartment T cell: all tissues
Toxicity Risks	<ul style="list-style-type: none"> • GVHD • CRS/neurotoxicity • On target toxicity
	<ul style="list-style-type: none"> • GVHD: T cell > NK cell (can be mitigated by editing) • CRS/neurotoxicity: T cell > NK cell • On target/off tumor toxicity: T cell > NK cell (persistence)

Our proprietary technology and differentiated approach

Advanced cell engineering expertise further differentiates our iPSC-derived allogeneic cell therapies

Our research and development team includes personnel with deep expertise in cell engineering. Cell engineering encompasses two critical components: genome engineering and protein engineering. We believe robust expertise in both these areas is of critical importance to realizing the potential of our iPSC-derived allogeneic cell therapy platforms. Genome engineering involves the manipulation of the cellular genome, through the use of genetic manipulation strategies including genetic knock-outs, knock-ins and HDR, to enable the creation of optimized cell products specifically tailored to address a particular disease. Protein engineering refers to the engineering and incorporation of CARs and other transgenes such as stimulatory cytokines, Allo-Evasion™ molecules, safety switches, and reporter proteins to generate highly functional cell therapies. We leverage these integrated capabilities to potentially enable our cell therapies to persist longer, to overcome detection by the host immune system and to elicit an enhanced therapeutic effect.

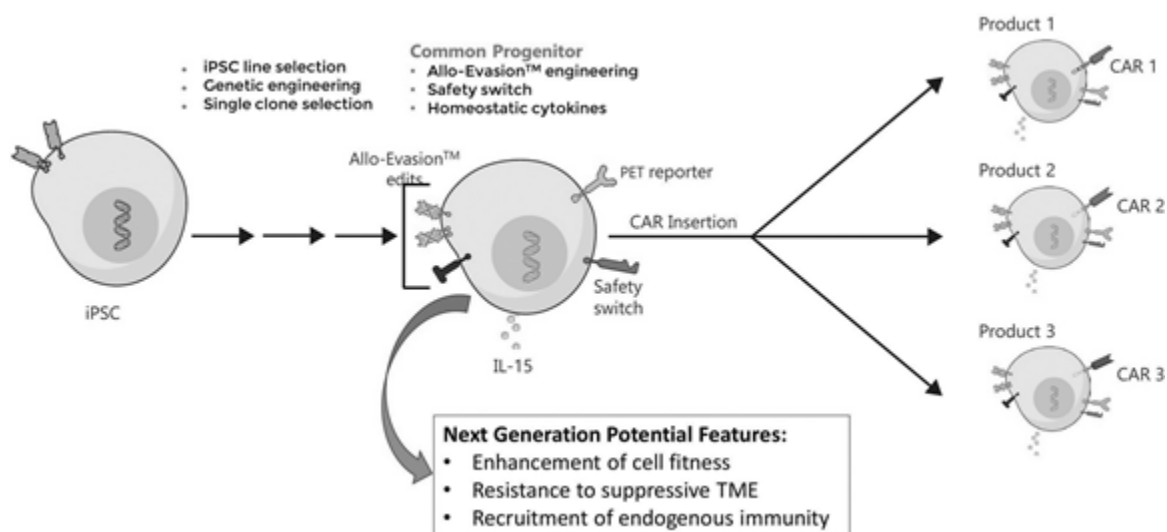
End-to-end development of product candidates



Common engineered iPSC progenitor

All of our product candidates include a set of core features designed to improve their functionality, safety profile, and persistence. These features include (i) our Allo-Evasion™ technology to enable the cells to avoid detection by the host immune system; (ii) a safety switch to allow for the rapid elimination of the cells from the patient if necessary; (iii) the inclusion of a homeostatic cytokine, IL-15, which promotes increased functionality and persistence *in vivo*, and is specific to NK cell therapy candidates; and (iv) a positron emission tomography, or PET, reporter molecule to allow for tracing of the distribution of cells upon administration, a capability we intend to include in our future product candidates. Our lead product candidate, CNTY-101, already incorporates the first three of these features. We have built all of these core features into a “common engineered iPSC progenitor” which is being utilized in the creation of a master cell bank. Further engineering to advance a development candidate for a specific target is then limited only to the addition of a CAR construct, allowing the generation of multiple product candidates targeting different indications from a single iPSC progenitor.

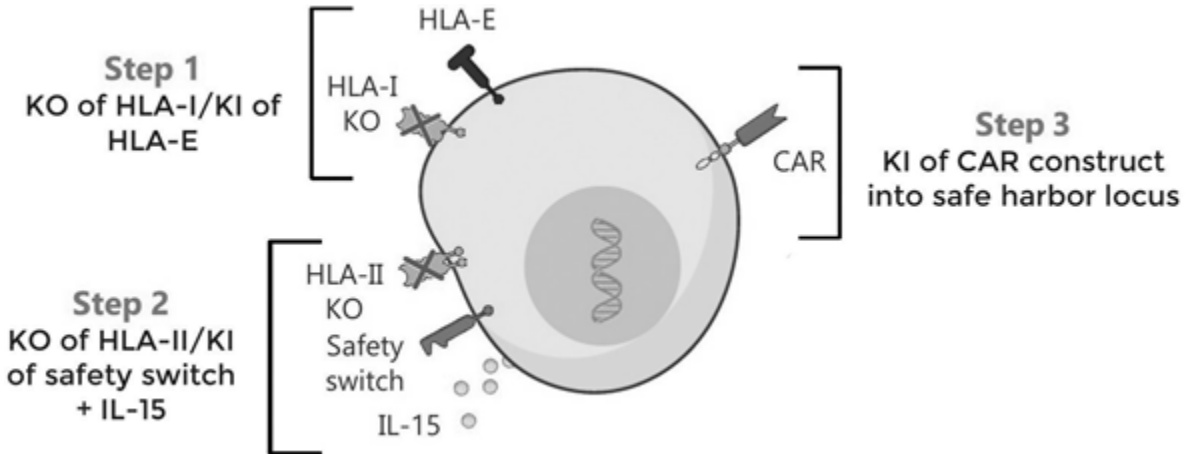
A single engineered iPSC progenitor can be used for multiple product candidates



Highly efficient engineering processes

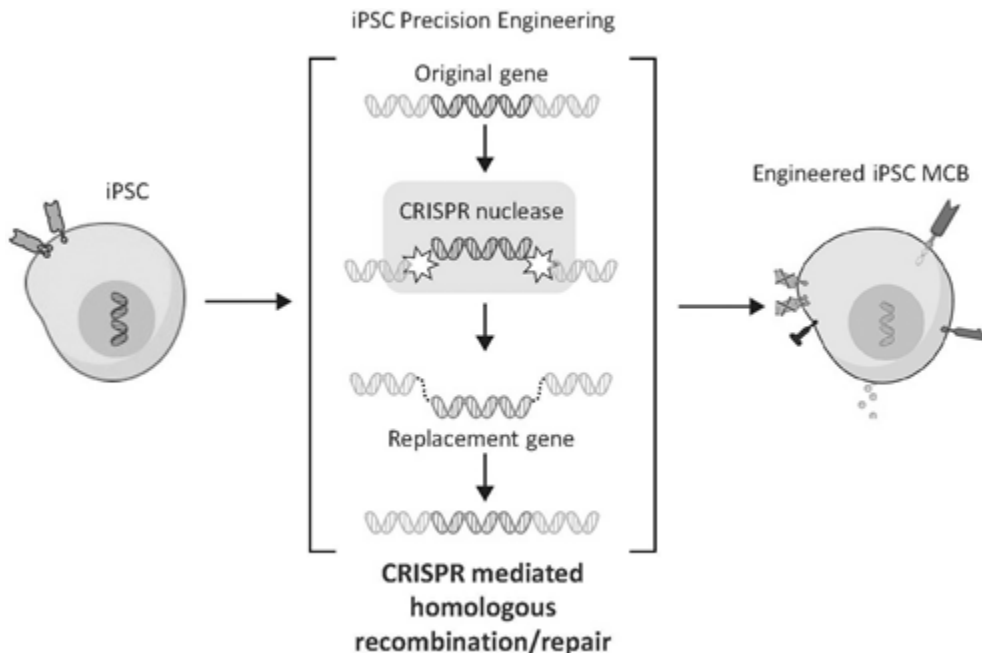
We have designed highly efficient engineering processes to generate our product candidates. During the engineering process, we frequently combine the knock-out of specific genes with the knock-in of transgenes we seek to express. In the case of CNTY-101, our lead product candidate, we incorporate six gene edits into three engineering steps to combine the knock-out of two genes (beta-2-microglobulin, or β 2m, and Class II Major Histocompatibility Complex Transactivator, or CIITA) with the knock-in of four transgenes (HLA-E, EGFR safety switch, IL-15, and CD19 CAR). The specific steps include (i) knock-out of β 2m to eliminate HLA-I expression with the knock-in of HLA-E, (ii) knock-out of CIITA to eliminate HLA-II expression with the simultaneous knock-in of the EGFR safety switch and IL-15 and (iii) knock-in of the CAR construct into the adeno-associated virus insertion sequence 1, or AAVS1, locus.

Engineering steps used to generate our CNTY-101 product candidate



These modifications are enabled by our innovative use of advanced biological engineering tools and technologies coupled with the application of internal expertise. We use CRISPR-based nuclease to enable precise editing of the iPSC genome. For CNTY-101 we used the nuclease Cpf-1 but have shifted to CRISPR-MAD7 for all subsequent programs for commercial reasons. In addition to our license from Inscripta, Inc. to use CRISPR-MAD7, we also have a license from Inscripta, Inc. to access the sequence of the enzyme which allows us to develop proprietary protocols to produce and purify the enzyme in-house as well as optimize its use to edit the genome. We have optimized our use of CRISPR-MAD7 to enable CRISPR-mediated homologous recombination and repair of multiple edits per iPSC.

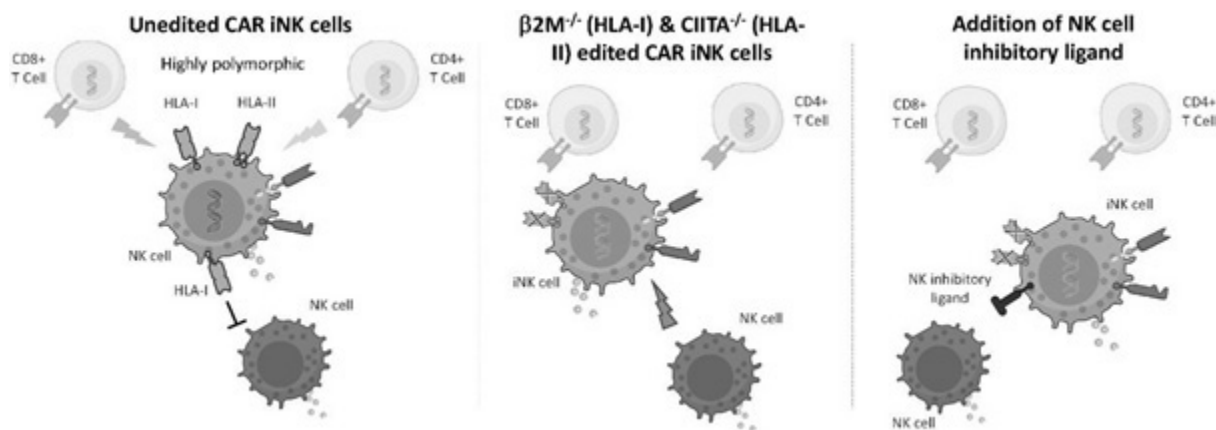
CRISPR mediated homologous recombination/repair



Advantages of our proprietary Allo-Evasion™ technology

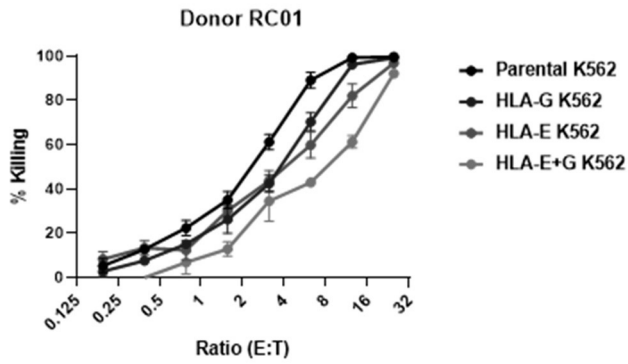
We believe that our Allo-Evasion™ engineering technology will allow our cell product candidates to escape recognition and destruction by the host immune system. We believe the reduction in allogeneic reactivity enabled by our use of this technology will allow us to conduct repeat dosing of our CAR-modified cell therapies to improve their therapeutic potential. In combination with the extended killing capability of optimized immune cells derived from single genetically engineered cell cloning, we envision utilizing repeat dosing to maximize durability of response and efficacy. Additionally, we believe this technology may permit dosing in patients with limited or no immune preconditioning regimens.

The potential of Allo-Evasion™ using NK inhibitory ligands

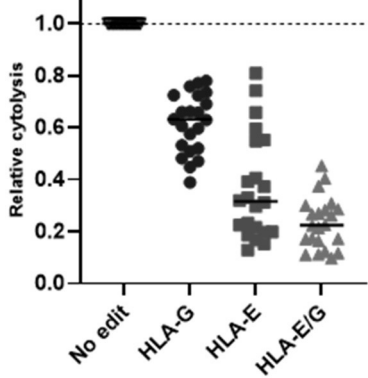


Preventing recognition of allogeneic iNK cell product candidates by T cells and NK cells from immune competent recipients. Genetic knockout of genes necessary for HLA I and II molecule expression removes the targets of recognition by allogeneic CD8⁺ and CD4⁺ T cells respectively, but renders the cells susceptible to killing by recipient NK cells (middle panel). Introduction of the NK inhibitory ligand HLA-E into the product candidate (right panel) delivers a negative signal to recipient NK cells that protects them from elimination.

The combination of HLA-E and HLA-G improves protection against host NK cell killing

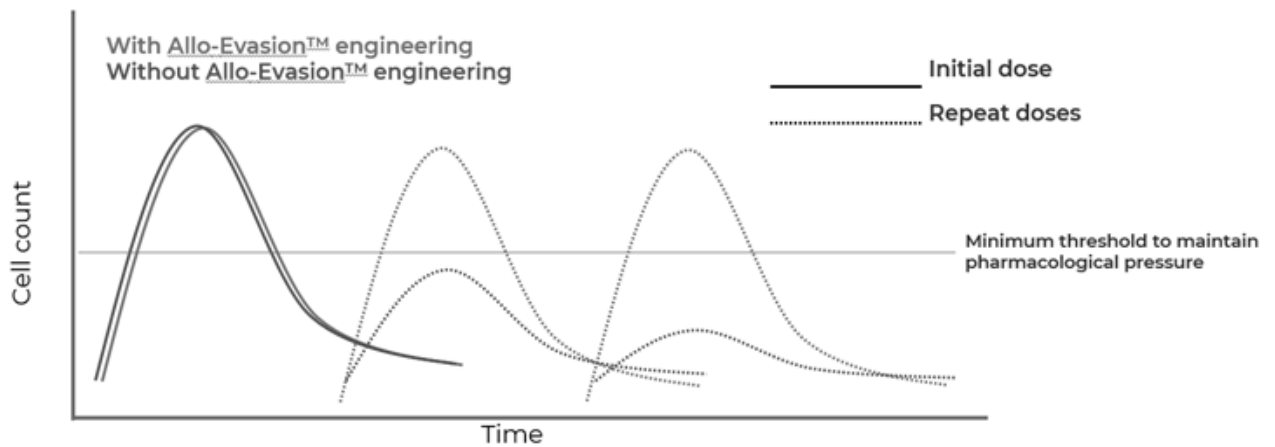


Agglomerated Data from 22 NK Cell Donors



HLA-E and HLA-G engage different receptors on NK cells including NKG2A, KIRs, and LIRs. The expression of NKG2A, KIRs, and LIRs varies among NK cells from different donors. The addition of HLA-G provides further protection against NK cell rejection to protect the cell therapy product candidate from elimination.

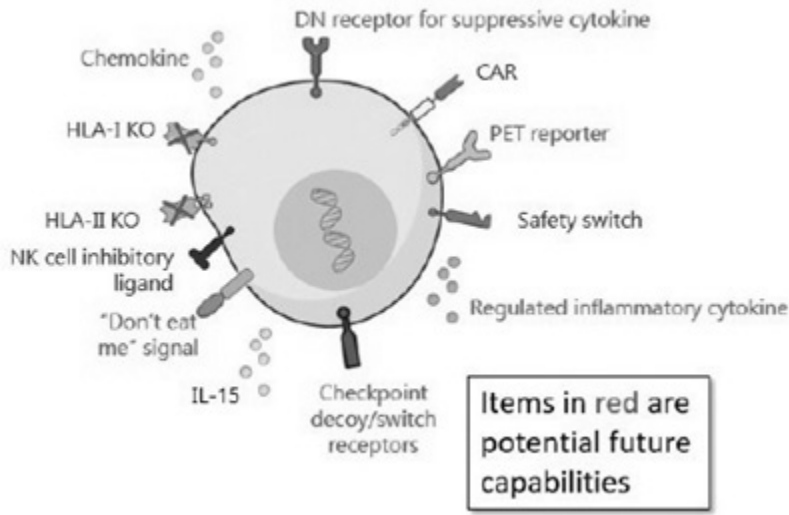
Illustrative potential of PK of Allo-Evasion™



Future generations of our cell therapies will embrace an extended range of capabilities

We envision future generations of our iPSC-derived allogeneic cell therapy platforms to incorporate additional capabilities. For instance, we are working on new approaches to lessen the effects of immunosuppressive cytokines, increase the secretion of pro-inflammatory cytokines, improve tumor homing through engineered receptors, convert immune checkpoints into co-stimulatory signals and recruit and activate endogenous immunity. We believe therapeutic enhancements such as these may be particularly relevant to cell therapies intended to treat solid tumors. In addition, we intend to engineer into our iPSCs a PET reporter molecule to enable the imaging of the patient to trace the distribution of the administered cells.

Future product candidates will be designed to embrace a potentially extended range of capabilities



To achieve our objective of discovering, developing and ultimately commercializing innovative cell therapies to treat cancer, we believe our core competencies and capabilities must extend well beyond a knowledge of iPSCs. In addition to deep capabilities in cell engineering, we believe the expertise needed in-house must also include iPSC biology, oncology, immunology, and manufacturing which are essential to engineer and develop cell therapies that have a high likelihood of clinical success.

Manufacturing, product quality and COGS advantages

We believe our use of iPSCs, which have unlimited replicative capacity, will allow us to develop a streamlined manufacturing process with scalability advantages while producing consistent, high quality, off-the-shelf products at reduced manufacturing costs. Given the unlimited replicative capacity of iPSCs, we believe that a single master cell bank can be used for the lifetime of the product.

We intend to develop expertise in scale-up technologies to enable optimal manufacturing scale. To achieve this goal, we are building a team of process development engineers and scientists as well as manufacturing and quality staff with experience in scaling cell expansion, cell harvest and final product filling processes. In addition, we are leveraging knowledge from other modalities, such as allogeneic mesenchymal stromal cell therapies, live virus vaccines, and therapeutic proteins such as monoclonal antibodies, to identify and develop scalable technologies intended to enhance our manufacturing and production processes. We believe that these efforts will ultimately result in efficiencies of scale and reduced manufacturing costs for our products, if approved. We intend to increase our investment in scale-up technology as our product pipeline advances through development towards commercialization.

We are investing in internal manufacturing facilities and capabilities that we believe will enable us to analyze, learn and adapt more rapidly, reduce manufacturing costs and increase control of development and manufacturing timelines for efficient clinical development and, if approved, commercial production of our product candidates.

A key aspect of our investment in internal manufacturing facilities and capabilities includes the construction of our Current Good Manufacturing Practices, or cGMP, manufacturing facility in Branchburg, New Jersey. We completed construction of this facility and it is now operational. This multi-product, multi-phase facility will have the capabilities and capacity to manufacture both iNK and iT cells, as well as other immune cell types, for complete optionality.

We believe that having access to our internal manufacturing facility, along with that of FCDI, will increase clinical supply availability and provide us with manufacturing and developmental flexibility. Furthermore, the expertise and learnings at each site can be leveraged for a greater probability of success on any project at either site. We believe this manufacturing network, along with our commitment to develop expertise in process scale-up and process understanding, will enable more efficient manufacturing and clinical development with lower cost of goods and consistent product quality.

Off-the-shelf commercialization opportunity for iPSC-derived allogeneic cell therapy platform derived product candidates

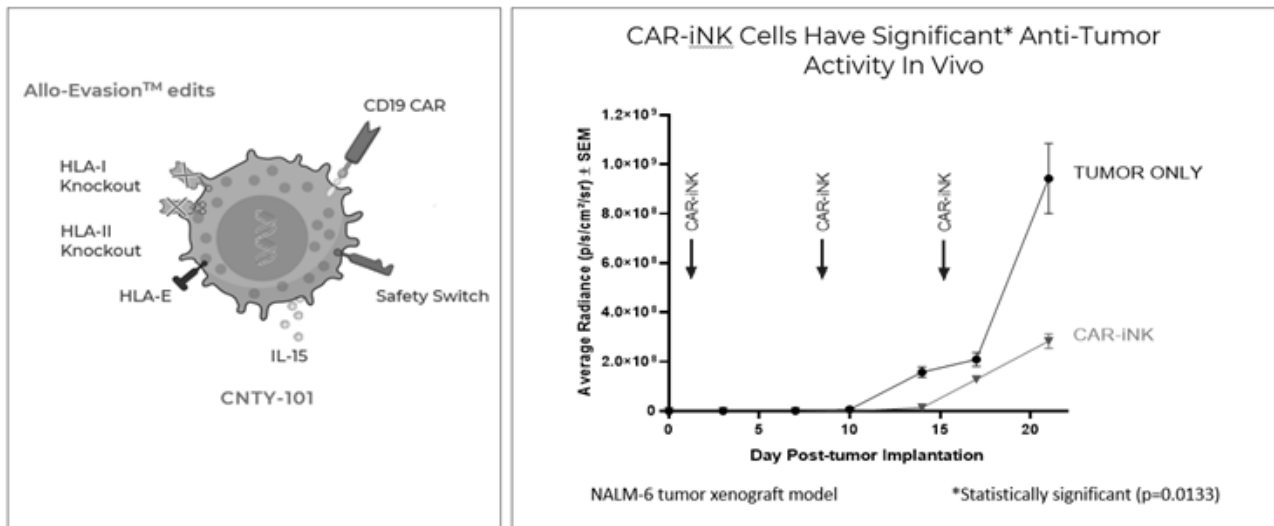
Allogeneic cells that can be cryopreserved offer the inherent advantage of off-the-shelf availability. Unlike autologous products, which cannot be produced until patient material is collected, the timing for manufacturing of allogeneic products is not dependent upon the patient. Primary donor cells can be collected and genetically modified well in advance of manufacturing, and manufacturing can be planned such that product is always readily available off-the-shelf for patients.

While cell therapies can be cryopreserved, cell quality may be negatively impacted by the freezing and thawing cycle. To combat this, we are making a significant investment in the development of robust and reliable freezing and thawing methods through rigorous examination of pre-freezing conditions that might affect the freeze/thaw, freezing parameters such as excipient types and concentrations, freezing temperature profiles, container configurations, and thawing conditions. The optimization of the many parameters that go into these steps will be enabled by the development of reliable quality testing procedures that measure the critical quality attributes of the product. We believe investing in these procedures and methods will help ensure that our cryopreserved cells maintain their quality through the freezing and thawing process.

Preclinical profiles or characteristics of development candidates

Our product platforms

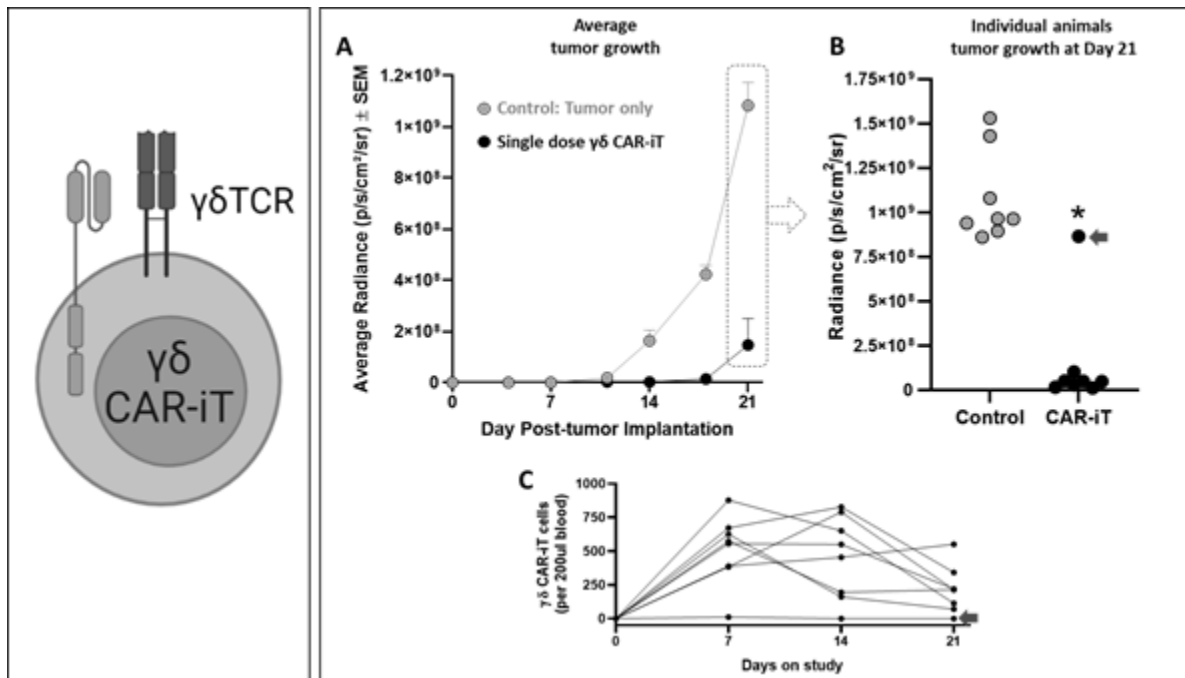
The iNK cell platform is our most advanced iPSC-derived cell platform



Left panel: cartoon representation of CNTY-101, our first iNK cell clinical candidate. Right panel: NALM-6 tumor growth inhibition of mice treated with CD19-CAR-iNK cells. The CD19-CAR-iNK cells were administered intravenously at 1×10^7 cells per mouse on Days 1, 8, and 15, as indicated by the arrows.

CD19-CAR-iNK cells demonstrate statistically significant ($p=0.0133$) anti-tumor growth inhibition compared to untreated control animals ("Tumor only"). Tumor burden was measured as the "Average radiance" of tumor-bearing mice.

The iT Cell platform is closely behind and making rapid progress



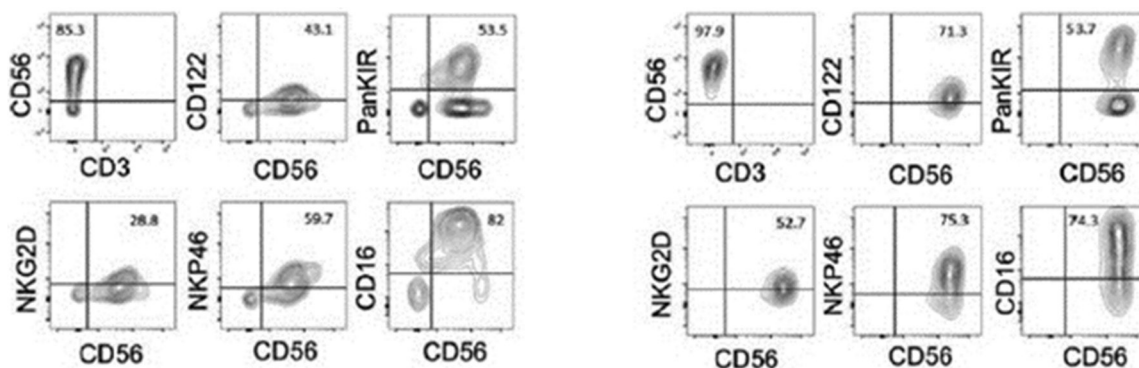
Left panel: cartoon representation of an iPSC-derived $\gamma\delta$ CAR-iT cell expressing a Trusted $\gamma\delta$ TCR and a CAR.. Right panel: **A.** Average NALM-6 (CD19+) tumor growth in mice treated $\gamma\delta$ CAR-iT cells (CD19-specific CAR). The $\gamma\delta$ CAR-iT cells were administered as a single intravenous dose of 1×10^7 cells per mouse on Day 1. The luciferase-labeled tumor cells were enumerated using in vivo bioluminescent imaging (magnitude of tumor growth reported as average radiance). **B.** Individual animal tumor growth on day 21. All 8 control mice (tumor only) exhibited aggressive tumor growth necessitating termination at day 21. The $\gamma\delta$ CAR-iT cells demonstrate statistically significant ($*p < 0.0001$) tumor growth inhibition compared to untreated control animals where 7 of 8 treated animals had deep responses at day 21. **C.** Detection of $\gamma\delta$ CAR-iT cells in peripheral blood of treated animals. Each line represents a single animal. Note: red arrow depicts that the one treated animal with aggressive tumor growth lacked detectable $\gamma\delta$ CAR-iT cells suggesting a technical problem with the intravenous injection of $\gamma\delta$ CAR-iT cells.

iPSC-derived iNK cell platform

Multiple processes have evolved to allow for the differentiation of an iPSC into an immune cell. Many of these approaches involve platforms that use various signaling molecules, referred to as feeder cells, to facilitate iPSC differentiation. We have engineered our iNK cell platform so that that it is feeder cell-free, which simplifies the manufacturing process and further reduces manufacturing costs.

Differentiation of iPSCs to functional immune cells involves a series of process stages conducted under strictly controlled conditions, with different cytokine mixtures introduced at different process stages. iPSCs are initially differentiated into hematopoietic progenitor cells, or HPCs, during which they assemble into three-dimensional aggregates. Cells from these aggregates bud off and are replated onto different tissue culture vessels coated with a specific extracellular matrix and exposed to a cytokine cocktail that promotes differentiation of the HPCs to NK cells, a process that takes fourteen days. After differentiation, cells are incubated for seven days to activate the NK cells. We are currently capable of achieving fully functional iNK cells from iPSCs in 30 days.

The phenotype of iPSC-derived NK cells is similar to primary human NK cells

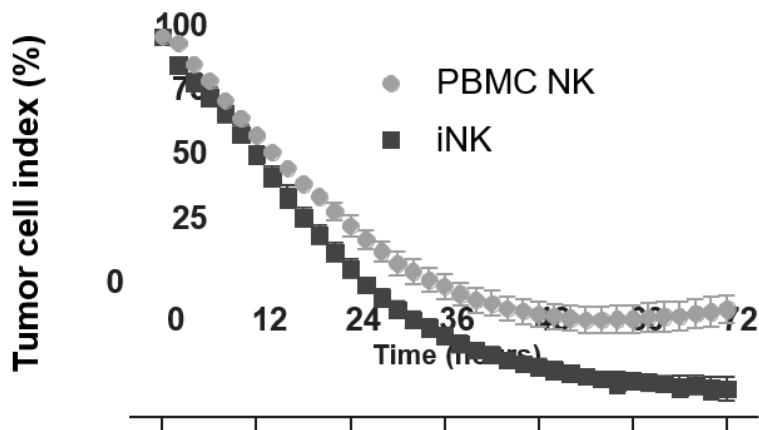


We have intentionally focused on the parameters that define immune cell functionality to direct internal development initiatives. This focus is intended to improve upon the intellectual property licensed from FCDI.

Accordingly, the parameters which have been the primary drivers of our activities have been cell persistence, killing potential and lack of induced toxicities, among other considerations. At the same time, we also characterize the cells phenotypically. As evidenced in the comparison presented above, NK cells derived from our iPSC- derived allogeneic cell therapy platforms are similar to primary human NK cells recovered from peripheral blood, with the phenotypic markers we evaluated displaying close alignment and the slight differences observed reflecting expected person-to-person variation.

Assessment of these cells' functionality demonstrates their potential for tumor cell cytotoxicity. Through a series of *in vitro* studies we evaluated the various mechanisms through which iNK cells eliminate tumor cells. As is presented below, one of the mechanisms used by NK cells to kill tumor cells involves the recognition of tumor cells lacking HLA-I by innate immune receptors. Using a leukemic cell line, K562, that lacks HLA molecules, we noted that the cell killing capacity of our iNK cells closely mirrored that of NK cells isolated from peripheral blood.

Our iNK cells kill K562 tumor cells similarly to PBMC peripheral NK cells

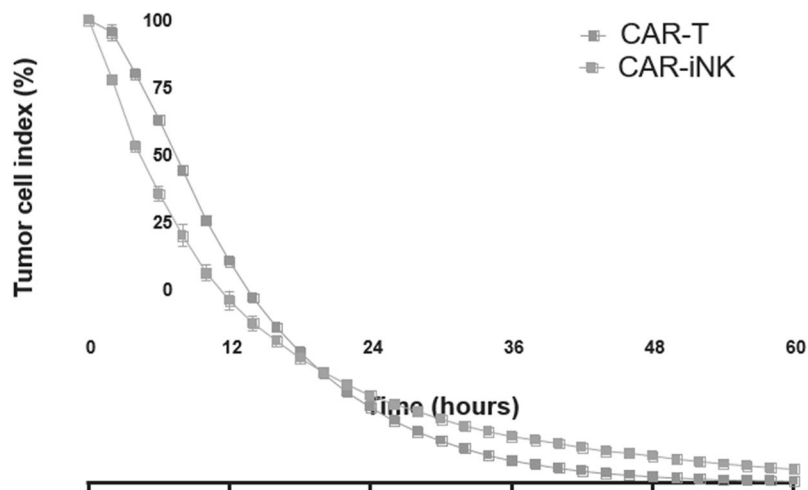


Century's iNK cells and peripheral blood mononuclear cell, or PBMC, NK cells were incubated with K562 tumor cells labelled with NuclightRed, or NLR, for 72 hours. Cocultures were imaged every 3 hours on the Incucyte live cell imager.

Upon cytolysis the target cells lose their NLR signal. Tumor cell index measures the density of tumor cells in the wells and is calculated as (tumor and iNK well at time x / tumor only well at time x) / (tumor and iNK well at first time point) * 100.

The addition of a CAR construct to the NK cell introduces a second mechanism by which tumor cells are eliminated. Our iPSC-derived NK cells demonstrated CAR-mediated tumor-cell killing of CD19 lymphoma cells, or Raji cells, comparable to peripheral blood CAR-Ts engineered with the same CAR construct.

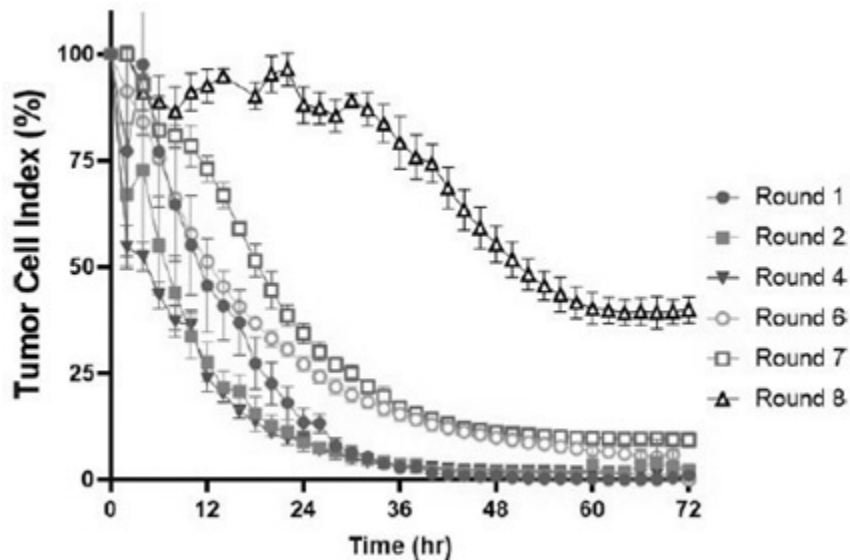
Our CAR-iNK cells kill lymphoma cells similarly to peripheral blood CAR-T cells



Our CAR-iNK cells and peripheral blood CAR-T cells were incubated with Raji tumor cells labelled with NLR for 60 hours. Cocultures were imaged every 3 hours on the Incucyte live cell imager. Upon cytolysis the target cells lose their NLR signal. Tumor cell index measures the density of tumor cells in the wells and is calculated as $(\text{tumor and iNK well at time } x / \text{tumor only well at time } x) / (\text{tumor and iNK well at first time point}) * 100$.

Our iNK cells also demonstrate the ability to engage and kill cancerous cells through multiple challenge rounds. In an evaluation of sustained killing capability, the results of which are presented below, we observed that iNK cells were successful in eliminating lymphoma cells through seven killing cycles before evidence of cell exhaustion and a decrease in cytolytic activity was observed. These results suggest that not only are the cells capable of retaining functionality and the ability to proliferate, but that the cytolytic machinery and signaling mechanism connecting target recognition to effector immune cells maintains sustained durability as well.

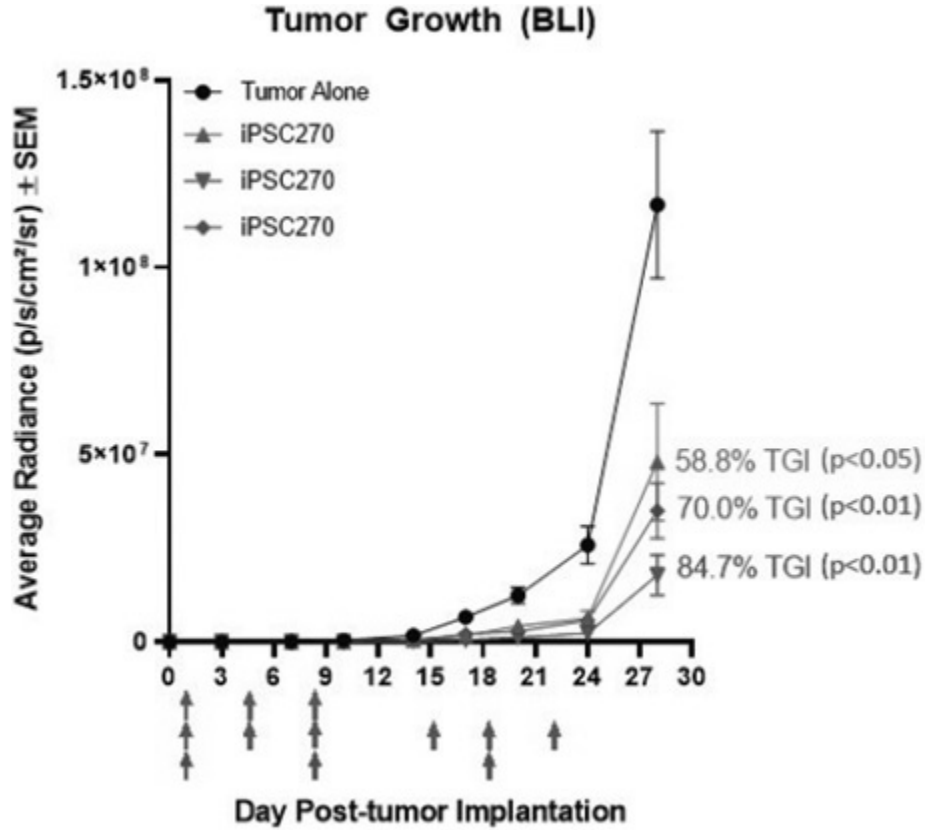
Our CAR-iNK cells have robust serial killing activity against lymphoma cells



Our CAR-iNK cells were incubated with Reh tumor cells labelled with NLR for multiple rounds of killing. Every 72 hours, the iNK cells were transferred to new tissue culture wells containing fresh tumor cells and allowed to kill for 72 hours. Cocultures were imaged every 3 hours on the Incucyte live cell imager. Upon cytolysis the target cells lose their NLR signal. Tumor cell index measures the density of tumor cells in the wells and is calculated as $(\text{tumor and iNK well at time } x / \text{tumor only well at time } x) / (\text{tumor and iNK well at first time point}) * 100$. Loss in killing activity was observed between rounds seven and eight.

The tumor-killing potential of our iNK cells was confirmed through *in vivo* evaluations. Raji lymphoma cells were administered intravenously to mice that were then dosed three consecutive days with both non-engineered and CAR- modified iNK cells, which had also been engineered to express the IL-15 cytokine. Tumor growth was then monitored over the following 20 days. As is illustrated in the graph below, the CAR-IL15 iNK cells showed meaningful anti-tumor activity, with tumor growth inhibition shown to be as high as 84.7%. Notably this study was conducted using bulk engineered material, prior to single cell cloning, which we believe has the potential to enhance anti-tumor activity.

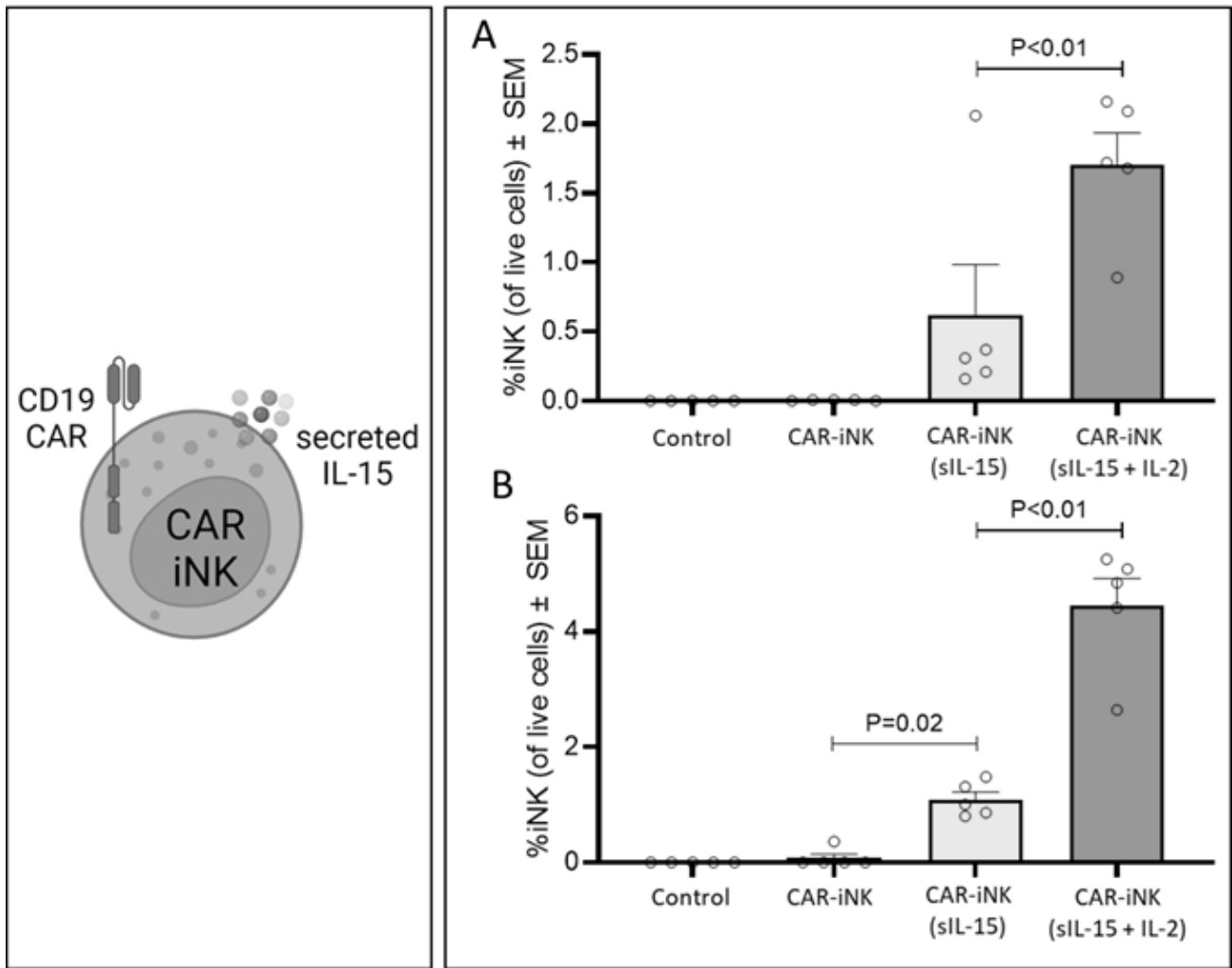
Our CAR-iNK cells have robust anti-tumor activity *in vivo*



The above chart displays Daudi tumor growth inhibition, or TGI, of mice treated with CD19-CAR-iNK cells administered under three different dose schedules. Average radiance, bioluminescence, or BLI of mice bearing intraperitoneal Daudi lymphoma xenografts, treated with CD19-CAR-iNK cells. Mice were implanted intraperitoneal with 1x10⁵ cells Daudi-Fluc cells on Day 0 and CD19-CAR-iNK cells were administered intravenously at 1x10⁷ cells per mouse on Days 1, 4, 8, 15, 18, and 22 as indicated by the arrows above.

In addition, to enhanced functionality, the engineered IL-15 has shown an identifiable benefit to persistence. As is presented in the illustration below, we observed viable iNK cells in the lungs and peripheral blood of mice 20 days after a single administration of CAR-iNK cells with IL-15, a result which was not noted in mice administered CAR-iNK cells without the addition of the cytokine.

The addition of a homeostatic cytokine significantly enhances iNK persistence

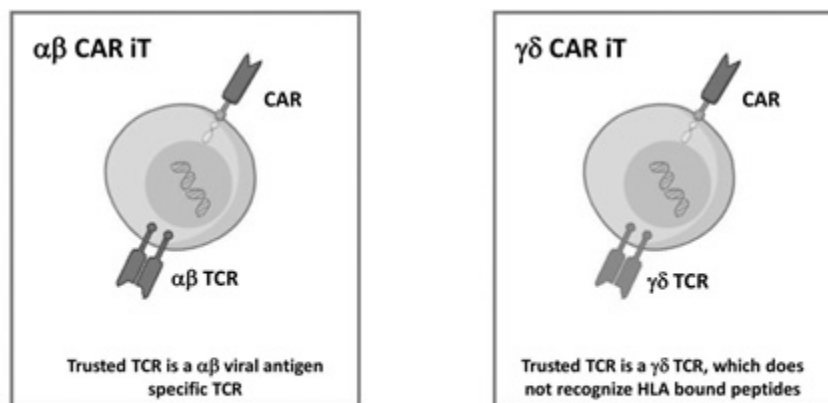


iNK cells were engineered to express a CD19-specific CAR molecule as well as secreted IL-15 to enhance iNK persistence *in vivo*. Mice received by intravenous injection: untreated (control), 1×10^7 CAR-iNKs (those lacking the secreted IL-15 [sIL-15] transgene), 1×10^7 CAR-iNKs-sIL-15, or 1×10^7 CAR-iNKs-sIL-15 plus additional recombinant IL-2 on days 1, 3 & 5 to enhance iNK persistence. In the upper panel **A** (peripheral blood) and the lower panel **B** (lungs), the presence of the sIL-15 transgene enhanced iNK persistence after 7 days. In both tissues, the addition of recombinant IL-2 via injection significantly enhanced persistence.

IPSC-derived iT cell platform

In addition to NK cells derived from our iPSC-derived allogeneic cell therapy platforms, we are also advancing the development of iPSC-derived T cells. The therapeutic properties offered by T cells, such as large *in vivo* expansion capacity, extended immune memory and the potential inclusion of engineered TCRs for additional tumor killing capacity, provide compelling reasons supporting their inclusion in our anti-cancer cell therapy arsenal. However, the development of allogeneic T cell-based therapies requires addressing unique challenges, such as GvHD. GvHD occurs when allogeneic donor T cells recognize an HLA class I and class II molecules on host cells and induce a severe and potentially life-threatening immune response against the host tissues. This is a challenge we plan to overcome by selecting Trusted TCRs that do not mediate GvHD.

We are exploring two major T cell subsets to develop our iT cell platform



Unique features of Century's iT cell platform:

- Retention of a functional TCR intended to improve iT cell differentiation and functionality
- Use of Trusted αβ and γδ TCRs, which are not expected to mediate GVHD

Proprietary Trusted TCR constructs enable our generation of TrueT™ cells

Many companies that are pursuing the development of allogeneic T cell therapies engineer T cell with an intentionally deleted TCR to eliminate the risk of GvHD. We have taken a fundamentally different approach; we believe that retention of the TCR is of significant importance, particularly to iPSC-derived T cells, as it helps with the differentiation and functionality of iPSC-derived T cells. We have devised strategies to utilize αβ or γδ TCRs on iPSC-derived T cells while minimizing risk of GvHD. In general, our approach capitalizes on selection of Trusted TCRs.

γδ T cells do not recognize hypervariable HLA class I or II receptors. Instead, γδ TCRs recognize ligands that are mostly invariant between individuals and these TCRs are unlikely to mediate GvHD. We leverage this characteristic of γδ chains to engineer iPSC lines with Trusted TCRs to create T-iPSC line that will be used to differentiate iT cell products. There are also special scenarios where an αβ TCR can have properties that lessen or eliminate the risk for GvHD, such in the case of some TCRs specific for viral antigens or the invariant αβ TCR expressed by, natural killer T cells, or NKT cells. We are pursuing γδ and αβ Trusted TCR approaches because γδ and αβ T cells have meaningfully different biological properties that can be explored for different tumor indications. Because of the importance of the TCR in normal T lymphocyte development, we call iPSC-derived T cells that express a Trusted TCR TrueT™ cells as a contrast to T cell engineered without a TCR.

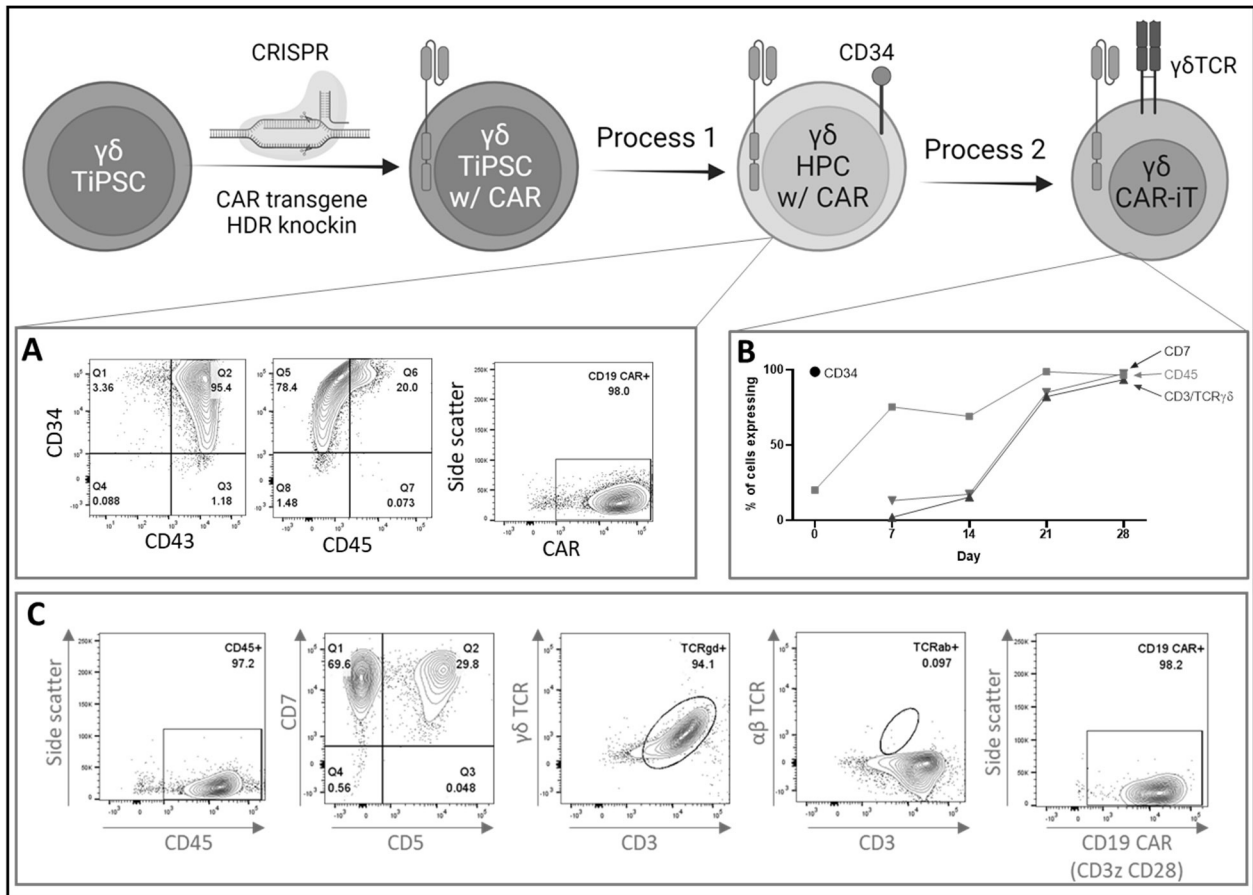
For any TrueT™ cell approach there are two main strategies that can be deployed to make iPSC-derived T cells. The first is to begin with a T cell from a healthy donor where the TCR identity is known (either a γδ T cell, NKT cell or conventional αβ T cell). Such T cells can be isolated, expanded, and purified. Then the desired T cell, which carries the desired rearranged TCR genes, is reprogrammed to generate iPSCs that carry the same TCR genes. We call these T cell-derived iPSCs T-iPSCs and they can be used to produce T cells with the desired TCR. We have developed proof of concept for this approach using T-iPSC lines that were reprogrammed using peripheral blood γδ T cells. A second approach is to use iPSC that were derived from a non-T cell and thus lack a rearranged TCR. In this scenario, the desired TCR is selected and synthesized as a transgenic construct. Then the desired TCR is engineered into iPSCs such that T cells that are produced from the iPSCs will carry the engineered TCR. We have developed proof of concept for approached using an iPSC line that was derived from non-T cells, in this case CD34+ peripheral blood hematopoietic cells, where we introduced a viral-specific TCR.

Differentiation of TrueT™ cells results in cells that co-express TCR and CD3 and can utilize an engineered CAR for target cell killing

The process for differentiating T cells from iPSC is a multistage *in vitro* system that includes several growth factors and key ligands that mimic the developmental signals found in the human thymus where T cells normally develop. We have refined protocols to differentiate T cells from both T-iPSC and TCR-engineered iPSCs.

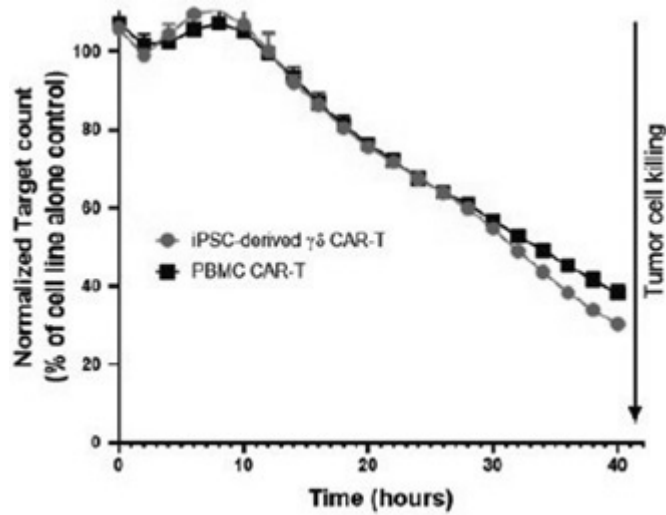
For $\gamma\delta$ T cells, the current process yields T cells that uniformly express the $\gamma\delta$ TCR and CD3. These iPSCs have been engineered to express a CD19 CAR for initial proof of concept studies. When the iPSC-derived $\gamma\delta$ T cells are exposed to CD19-expressing lymphoma cells, the lymphoma cells are killed in an antigen-specific manner.

Differentiation of $\gamma\delta$ CAR-iT cells from T-iPSC



A T-iPSC line that was derived from a V γ 9/V δ 2 $\gamma\delta$ T cell was engineered with CRISPR to introduce the CAR transgene. The T-iPSC were then subjected to two sequential differentiation processes. **A**. First, the TiPSC were cultured under conditions that cause them to differentiate into CD34+ hematopoietic progenitor cells (HPCs) which have multilineage capability. **B**. Next, T lineage commitment was enforced during process 2 where the cells were differentiated into uniform CD3+ CD45+ CD7+ T cells over the course of 28 days. **C**. The day 28 T cells were assessed by flow cytometry and the data indicates that the cells express T lineage markers (CD3, CD7, and CD5) as well as the $\gamma\delta$ T cell receptor but not the $\alpha\beta$ T cell receptor. The T cells also retained high expression of the CAR molecule.

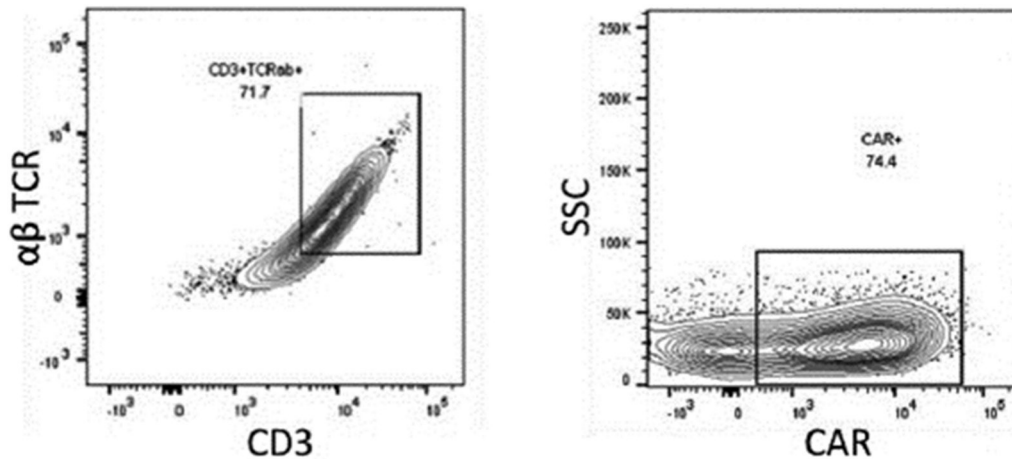
$\gamma\delta$ CAR-iT cells kill CD19-expressing lymphoma cells



CAR-iT cells were used in a tumor cell killing assay on an IncuCyte instrument. For this study, Reh cells, a CD19- expressing lymphoma line was used. PBMC CAR-T are PBMC-derived T cells that have been engineered to express the same CAR molecule, which have been added as a control for this study. When CD19-positive Reh cells were exposed to CAR-T cells, both iPSC-derived and PBMC-derived CAR-T cells mediated tumor killing.

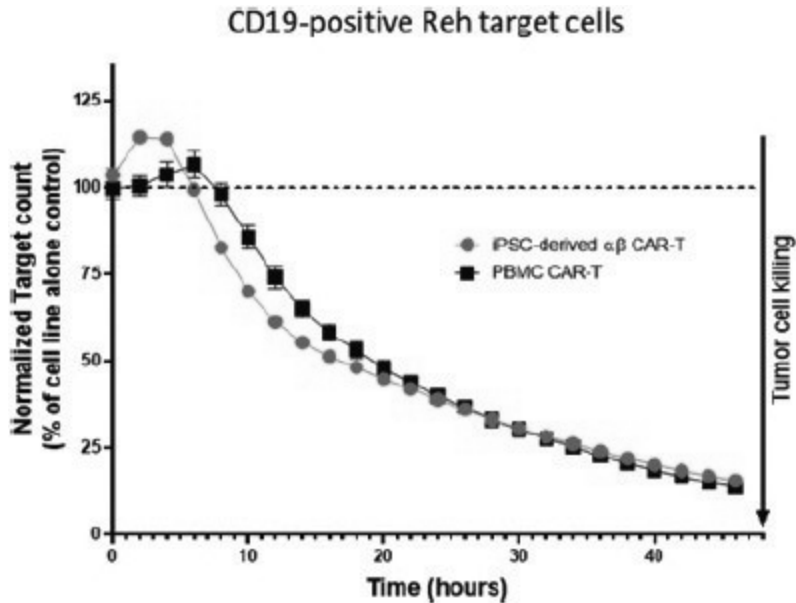
For conventional $\alpha\beta$ T cells, the current process yields iT cells that uniformly express the $\alpha\beta$ TCR and CD3. These iPSCs were also engineered to express a CD19 CAR to evaluate their tumor cell killing activity. When the iPSC- derived $\alpha\beta$ T cells were exposed to CD19-expressing lymphoma cells, the lymphoma cells were killed in an antigen- specific manner.

Differentiation of $\alpha\beta$ CAR-iT cells from T-iPSC

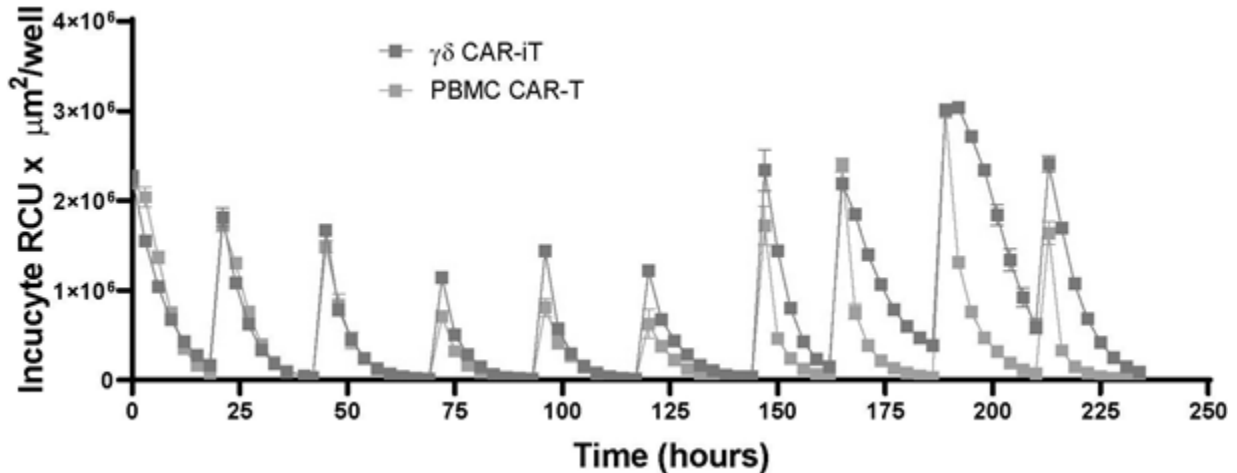


A T-iPSC line that was derived from a $\alpha\beta$ T cell was used to differentiate $\alpha\beta$ T cells using a process that takes approximately five to six weeks. At the end of the process, cells were collected and stained for flow cytometry. The left panel demonstrates co-expression of CD3 and the $\alpha\beta$ TCR on the cell surface of resulting iT cells. Because the T-iPSC line was also engineered with a CAR transgene, the CAR protein was also detected on the surface of these iT cells (right panel).

$\alpha\beta$ CAR-iT cells kill CD19-expressing lymphoma cells



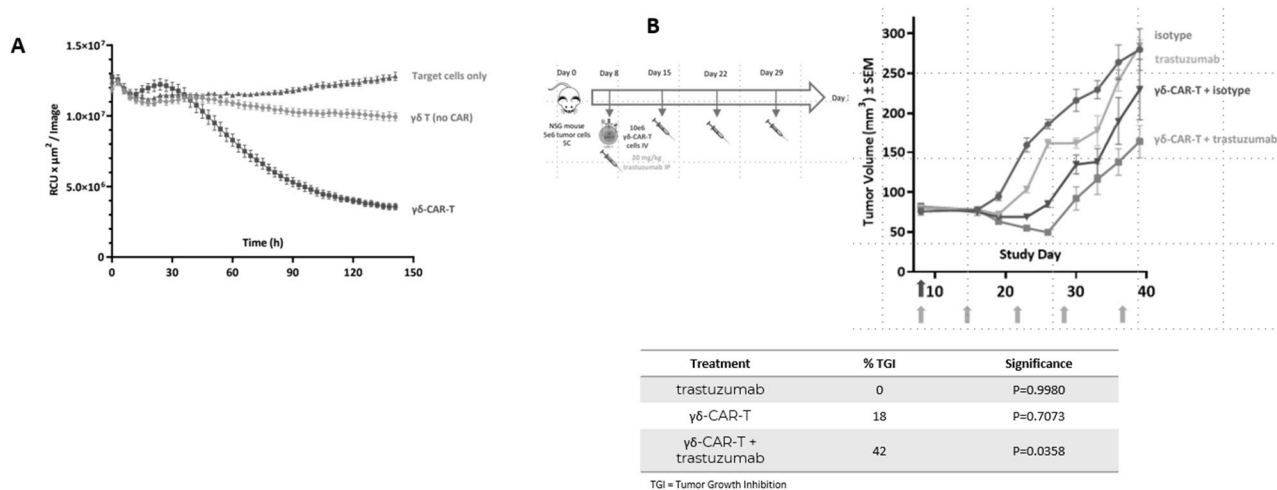
CAR-iT cells were used in a tumor cell killing assay on an IncuCyte instrument. For this study, Reh cells, a CD19- expressing lymphoma line was used. PBMC CAR-T are PBMC-derived T cells that have been engineered to express the same CAR, which have been added as a control for this study. When CD19-positive Reh cells were exposed to CAR-T cells, both iPSC-derived and PBMC-derived CAR-iT cells mediated tumor killing.



Serial killing of CD19⁺ tumor cells by CAR- $\gamma\delta$ -iT cells is comparable to PBMC-derived CAR-T cells. The serial killing assay was performed using an IncuCyte instrument where viable tumor cells expressed Nuclight Red and were enumerated every 3 hours based on Red Calibrated Units, or RCU, a measure of total red fluorescence. At the beginning of the culture, 1e5 CAR- $\gamma\delta$ -iT or CAR-T were added to each well followed by addition of 2e4 NALM-6 target cells (Nuclight Red⁺). Cells were cultured in complete medium with 10 ng/ml rhIL-15. Every 24 hours, 2e4 fresh NALM-6 cells were added to the culture and data was recorded for 10 days. Increasing RCU indicates daily addition of new targets and/or outgrowth of tumor cells. Decreasing RCU indicates tumor cell killing by $\gamma\delta$ CAR-iT cells or PBMC CAR-T cells.

Collectively, we have made significant progress in deriving iPSC lines that carry Trusted TCRs as well as refining the differentiation process to generate TrueT™ cells that express a TCR and a CAR. The cells mediate robust killing of lymphoma cells when their CAR is engaged. We believe that we have put in place the fundamental building blocks to continuing the advancement of our iT cell platform to generate iPSC-derived $\alpha\beta$ and/or $\gamma\delta$ T cell therapies for different tumor indications.

iPSC-derived GD T cells effective at tumor control as monotherapy and in combination with antibody



A. $\gamma\delta$ -EGFR-CAR-T cells demonstrate significant CAR killing of ovarian spheroids B. $\gamma\delta$ CAR-T demonstrate additive efficacy in combination with trastuzumab

Our development candidates

We are assembling a portfolio of allogeneic iNK and iT cell therapy product candidates across solid tumor and hematological malignancies. This pipeline is comprised of cell therapies that will address diseases where we believe current therapies are inadequate. All product candidates incorporate our proprietary Allo-Evasion™ technology to avoid host rejection and potentially increase the durability of clinical responses. Our lead product candidate, CNTY-101, targeting CD19 positive lymphomas is currently being evaluated in a Phase 1 clinical trial. Our second product candidate, CNTY-102, is designed to further improve B-cell malignancy treatment. Our third product candidate, CNTY-107, is a Nectin-4 targeted product candidate in solid tumors. Our fourth product candidate, CNTY-104, is being developed in collaboration with Bristol-Myers Squibb to treat AML We are also developing CNTY-106 in collaboration with Bristol-Myers Squibb for multiple myeloma.

Our development programs consist of the product candidates illustrated in the pipeline chart below:

Product	iPSC Platform	Targets	Indications	Discovery	Preclinical	Clinical			Collaborator
						P1	P2	P3	
CNTY-101	iNK	CD19	B-Cell Malignancies						
CNTY-102	iT	CD19 + CD22	B-Cell Malignancies						
CNTY-107	iT	Nectin-4	Solid Tumors						
Programs in Collaboration									
CNTY-104	iNK/iT	Multi-specific	Acute Myeloid Leukemia						Bristol Myers Squibb
CNTY-106	iNK/iT	Multi-specific	Multiple Myeloma						Bristol Myers Squibb
Research Programs									
Discovery	iNK/iT	TBD	Hematological / Solid Tumors						

Solid Tumors Hematologic Tumors

- (1) We are party to an option agreement with Bayer HealthCare LLC, or Bayer, pursuant to which Bayer was granted certain bidding rights relating to the potential transfer of rights with respect to certain product candidates being researched and developed by us which are comprised of iNK cells, macrophages or dendritic cells, and any other product candidate comprised of iNK cells that we develop in the future. CNTY-101 is no longer included in the agreement. Bayer's rights under the option agreement are subject to important limitations. See “—Licensing, partnership and collaboration— Bayer HealthCare LLC—Option Agreement” for more information.
- (2) We entered a collaboration with Bristol-Myers Squibb to develop and commercialize up to four iNK or iT candidates, including CNTY-104 and CNTY-106. See – Licensing, partnership and collaboration – Bristol-Myers Squibb for more information.

CNTY-101: Our CAR-iNK candidate targeting CD19 for relapsed, refractory B-cell lymphoma

Disease background

B-cell lymphoma is a cancer that affects B lymphocytes that make up part of the immune system. It generally originates in the lymph nodes. B-cell lymphoma includes both Hodgkin's disease and approximately 80% to 85% of patients diagnosed with non-Hodgkin's lymphoma, or NHL, a disease classification that includes more than 50 different hematological malignancies. In the United States, approximately 70,000 cases of NHL are diagnosed each year and the number of new diagnoses is increasing each year as the median age in the United States increases. 30-40% of these patients will relapse or have disease refractory to current treatments.

Current treatment and shortcomings

Treatment of non-Hodgkin's lymphoma is dependent on disease designation. Indolent disease may be treated with localized radiation or simply monitored for disease progression, at which time the disease is often treated with rituximab, with or without chemotherapy. Aggressive disease is treated with chemotherapy if diagnosed in the earlier stages of disease progression or with combination of rituximab and chemotherapy if diagnosed in the more advanced stages. While aggressive NHL is curable, indolent disease currently is not.

In aggressive large B-cell lymphomas, existing FDA-approved CD19 CAR-T cell therapies show overall response rates of 50-80%, complete response rates of 30-40%, and where longer term follow up data is available, a three year survival rate of 47%. They are also shown to be effective in aggressive and indolent lymphoma subpopulations and are in active testing in second line lymphoma. While these treatments have

transformed care, significant medical need still exists in the relapsing and progressing patients that remain, with additional limitations of the autologous therapies described herein. As such, there is active investigation of several allogeneic B-cell targeting CAR-T therapies and B-cell targeting CAR-NK cell therapies in lymphoma.

Our therapeutic approach and development program

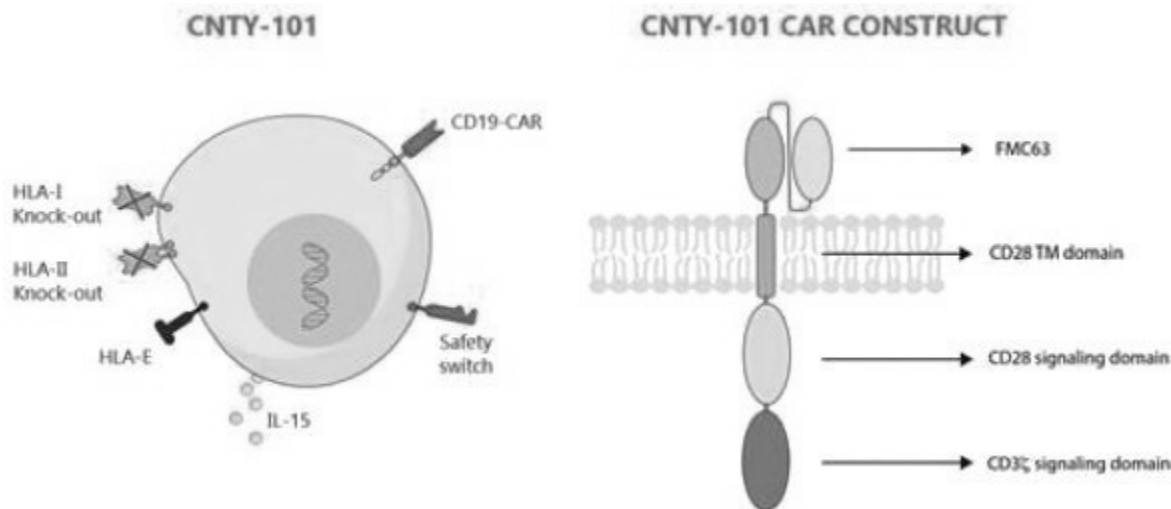
Our lead product candidate, CNTY-101, is an allogeneic, iPSC-derived CAR-iNK cell product for the treatment of CD19 positive B-cell lymphomas. CNTY-101 has been engineered with the following features:

- expression of CD19 CAR to target malignant B cells, our CAR construct uses the FMC63 scFv and the signaling domains of CD28 and CD3 ζ ;
- knock-out of HLA-I and HLA-II to escape elimination by the patient's CD8 and CD4 T cells;
- knock-in of HLA-E to avoid killing by the patient's NK cells;
- expression of IL-15 to provide homeostatic cytokine support to improve persistence and functionality; and
- incorporation of an EGFR safety switch to allow for elimination of the product if necessary.

The safety switch consists of a shorter version of the extracellular domain of EGFR, which binds to clinically approved antibodies, such as Cetuximab, which can trigger product elimination through antibody-dependent cellular cytotoxicity, or ADCC, or antibody-dependent cellular phagocytosis, or ADCP.

We believe the modifications described above may lead to treatments with greater potency, persistency and durability. As the CD19 target and the FMC63-CD28z CAR have been validated by existing FDA-approved CAR-T therapies, we believe target-related risks have been significantly diminished, as the approved CAR-T cell products have been shown to improve remission rates and improve overall survival in patients with various B-cell malignancies. The inclusion of a validated CAR construct in our first product candidate eliminates a key variable, i.e. the performance of a novel CAR construct, better enabling our Allo-Evasion™ engineered iNK platform to be validated in the initial studies. The validity of this therapeutic approach is further supported by a M.D. Anderson clinical trial of CAR-NK cells targeting CD19 used in the treatment of relapsed or refractory NHL and chronic lymphocytic leukemia, or CLL, patients. In that trial, eight of the 11 patients responded to treatment with seven patients achieving complete remission.

CNTY-101 and CD19 CAR construct



Left panel: engineered features of CNTY-101. Right panel: structure of the CD19 CAR construct used in CNTY-101

We completed engineering of iPSC lines from five different donors and single cell cloning of numerous iPSC lines. The single cell clones underwent genotype and phenotype identity, purity, safety, manufacturability, and *in vitro* and *in vivo* functional testing. CD19 iNK single cell clones demonstrate significant cytotoxicity *in vitro* comparable to CAR-T controls, and numerous cycles of serial killing after repeated challenge with lymphoma cells. CNTY-101 single cell clones also demonstrate IL-15 expression and persistence *in vivo*, as well as *in vivo* tumor growth inhibition. We received safe to proceed notification from the FDA in August 2022 and have advanced CNTY-101 into a Phase 1 clinical trial named ELiPSE-1, in which we began dosing patients in February 2023.

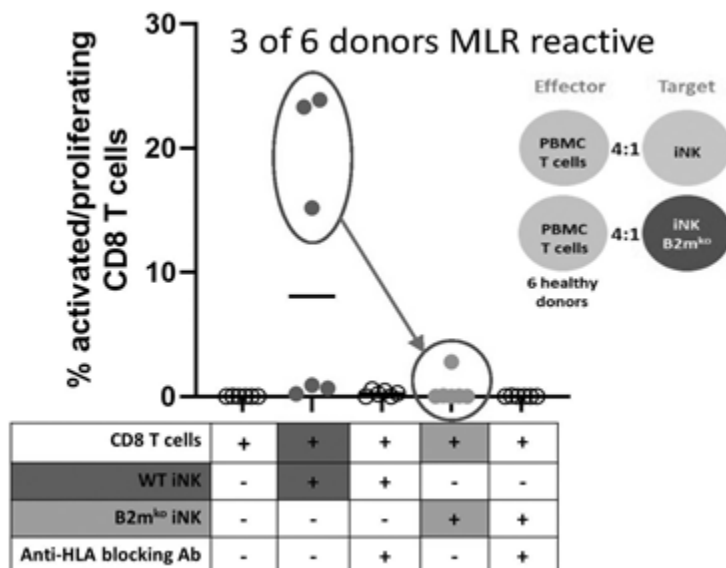
Preclinical studies and selection of the final product candidate for CNTY-101

To identify the CNTY-101 clinical candidate, we engineered iPSC lines from five different donors. The initial characterization studies were done with bulk cells prior to single cell cloning (bulk-engineered cells), and we generated additional data with single-cell clones. To identify the candidate, we narrowed down to six clonal cell lines derived from two donors. The initial evaluation of the Allo-Evasion™ features and safety switch was done on bulk-engineered iPSC lines.

Allo-Evasion™ studies with bulk-engineered CAR-iNK cells

To prevent recognition of our CAR-iNK cells by CD8 T cells from the patient, we eliminated the expression of the HLA-I by deleting $\beta 2m$, a protein that is required for the expression of HLA-I molecules on the cell surface. Our current Allo-Evasion™ data has been generated with bulk-engineered iNK cells prior to single cell clonal selection. However, even with bulk-engineered cells where a small percentage of cells (1.6%) in the population still retains HLA-I, it is clear that the deletion of $\beta 2m$ significantly diminishes the allo-reactivity of allogeneic CD8 T cells against our iNK cells. In the final clinical candidate clones for therapeutic product candidates, HLA-I will be uniformly absent from all iNK cells.

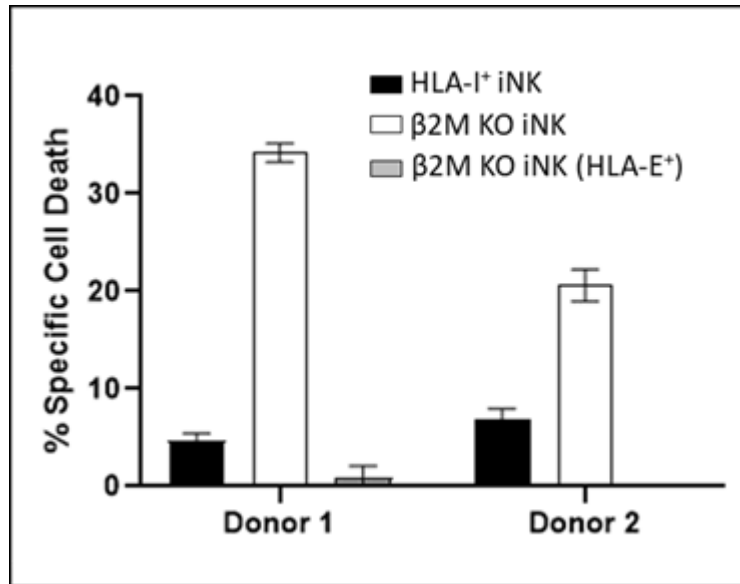
Elimination of HLA-I prevents allogeneic immune recognition of iNK cells by CD8 T cells



Elimination of HLA-I prevents allogeneic immune recognition of iNK cells by CD8 T cells. To determine if removal of HLA-I via $\beta 2m$ knock-out prevents recognition of iNK cells by allogeneic T cells, a mixed lymphocyte reaction, or MLR, was performed with CD8 T cells from six allogeneic donors. Allogeneic T cells show virtual no proliferation when incubated with iNK cells that do not express HLA-I (B2Mko iNK), in contrast with iNK cells expressing HLA-I (iNK).

Deletion of HLA-I prevents the recognition of our iNK cells by allogeneic T cells, but on the other hand, it exposes the iNK cells to killing by the patient's NK cells. NK cells can sense the lack of HLA-I as a danger signal (missing self- hypothesis) and eliminate HLA-I negative cells. As part of our Allo-Evasion™ technology, we engineered the expression of HLA-E, a monomorphic MHC Class I related molecule to prevent the killing of the HLA-I null iNK cells. HLA-E engages an inhibitory receptor, NKG2A on NK cells and prevents their cytolytic activity. Our data with engineered iNK cells indicates that HLA-E is effective in mitigating the killing of the null iNK cells.

Expression of HLA-E prevents killing of iNK cells that have been engineered to prevent HLA-I expression



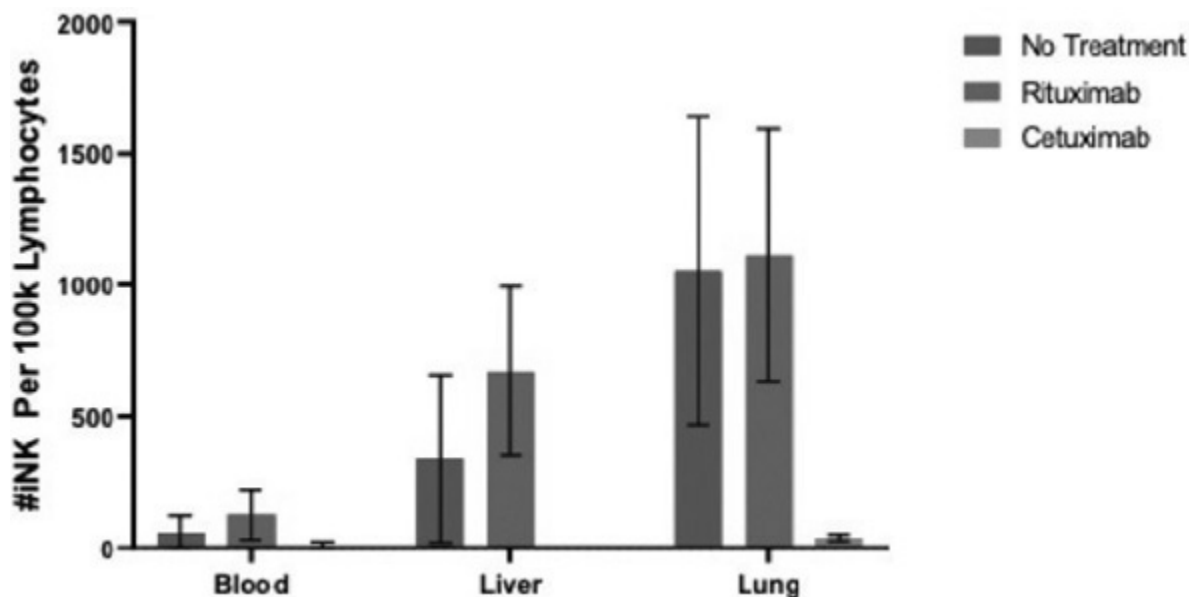
iNK cells were derived from three different iPSC lines. A non-engineered iPSC line that carries an intact β 2M gene was used to prepare iNK cells that are HLA-I⁺. A version of the same iPSC line was then engineered to knockout (KO) the gene β 2M in order to ablate HLA-I expression. Finally, a version of the same iPSC line was engineered to both delete β 2M and transgenically express the gene HLA-E. iNK cells that express HLA-I are mostly spared from lysis in an allogeneic co-culture with PBMC (including NK cells) from two different donors. However, iNK cells lacking HLA-I (β 2M KO) are lysed by NK cells. Finally, expression of HLA-E on iNK cells that lack other HLA-I molecules are spared from lysis by allogeneic NK cells.

Evaluation of the EGFR safety switch with bulk engineered CAR-iNK cells

CNTY-101 is engineered with a safety switch that can be triggered to eliminate the cells if ever necessary. Our switch includes a shorter version of the EGFR extracellular domain, anchored to the plasma membrane. This form of EGFR binds to cetuximab, a clinically approved antibody we plan to use as a trigger for the safety switch.

Cetuximab engages Fc γ R on innate immune cells, such as NK cells and macrophages, to eliminate EGFR-expressing cells through ADCC or ADCP. Our preliminary data from *in vivo* studies indicates that the cetuximab effectively triggers the elimination of iNK cells engineered with our EGFR safety switch from different tissues including blood, liver, and lungs.

Elimination of iNK cells using EGFR safety switch

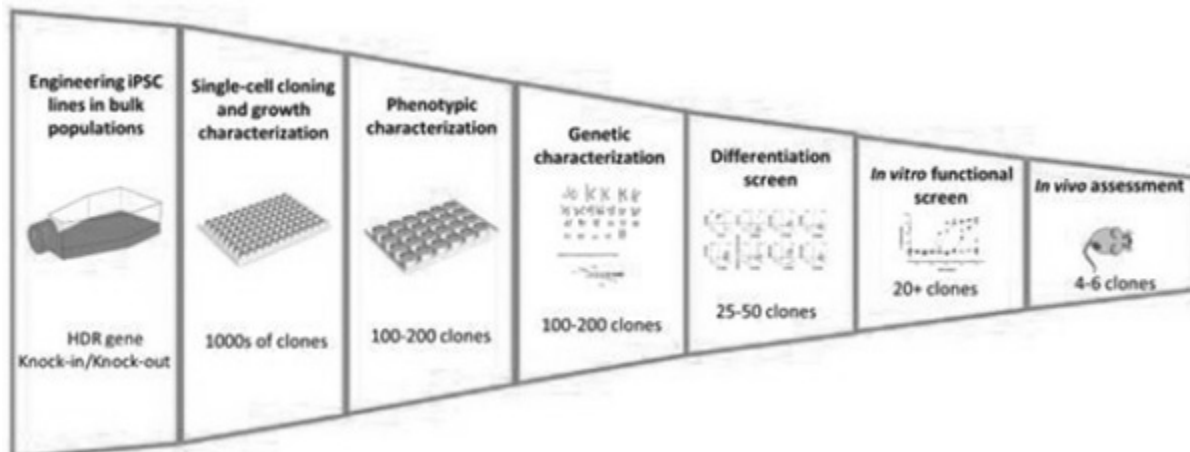


NSG mice were intravenously infused with 1×10^7 CD19iNK and one day later treated with 40 mg/kg cetuximab or rituximab (as a control). On Day 8, mice were humanely euthanized and whole blood, liver, and lung samples were collected and analyzed for the presence of iNK cells.

Single-cell cloning of engineered iPSC from different donors to identify the final clinical candidate

We completed the single cell cloning of engineered iPSC lines from five different donors. The single cell clones were characterized for the expression of NK cell markers and the inserted transgenes. Selected clones were then characterized genetically by karyotype analysis, copy number variations, transgene copy number and insertion fidelity, and, finally, whole genome sequencing. The phenotype and genotype positive clones were progressed to an iNK differentiation, *in vitro* functional and manufacturability screens. We narrowed down the number of candidates to six clonal lines from two different donors. These lines were evaluated *in vivo* for final clinical candidate selection, and have advanced CNTY-101 into a Phase 1 clinical trial, ELIPSE-1, and began dosing patients in February 2023.

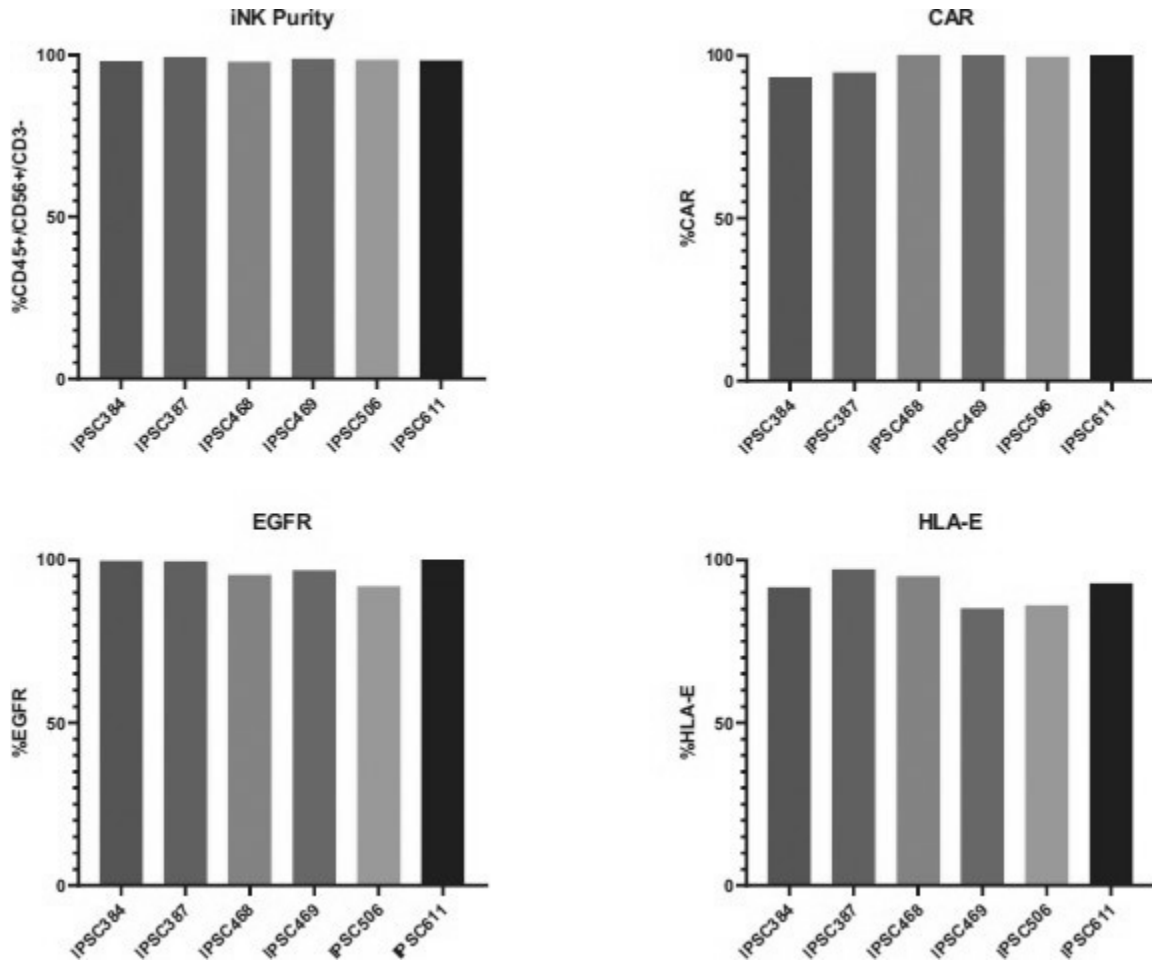
CNTY-101 lead discovery funnel to identify final clinical candidate



Selected single-cell clones express engineered transgenes in virtually all cells after expansion

We ran a series of phenotypic assays and transgene expression characterization to narrow down the list of top candidates to six iPSC lines. After expansion in culture, the cell populations derived from single cell clones are highly uniform. Virtually all cells from all clones are CD45+, CD56+, CD3- indicating that these cells are NK cells. In addition, the cells uniformly express the CAR, HLA-E, and EGFR (safety switch) transgenes indicating that our product candidate clones are highly uniform when assessed for phenotypic markers.

Transgene expression and purity of iNK cells

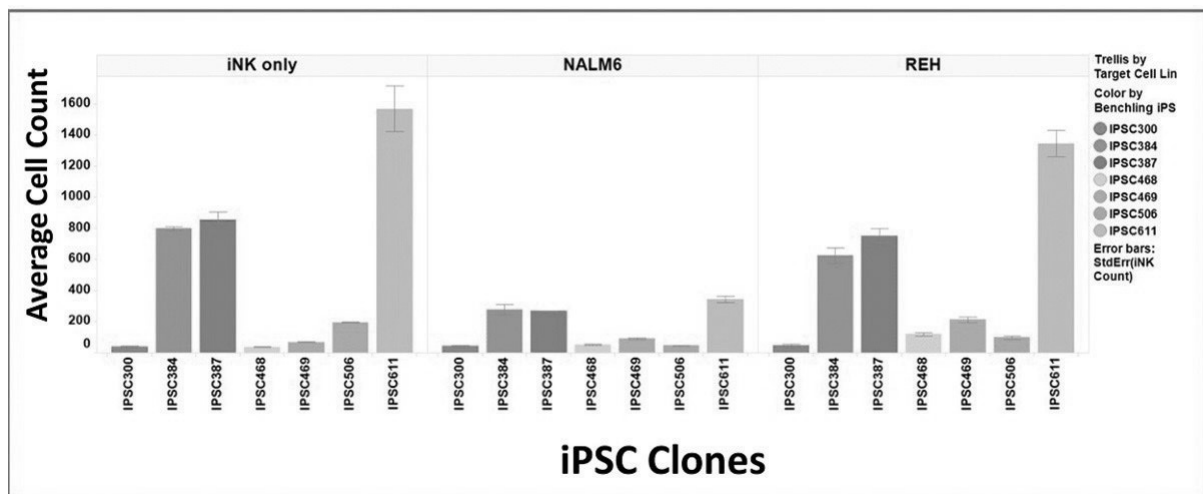


Transgene expression and purity of day 21 iNK clones as measured by flow cytometry. All clones were >97% iNK cells defined as live/CD45+/CD56+/CD3- (top left panel). Transgene expression (CAR, EGFR, and HLA-E) was measured on total live population after expansion of the single cell clones.

Functional analysis of iNK cells generated from individual iPSC clones reveals meaningful differences in the *in vitro* persistence and killing capacity of clinical candidates.

In addition to assuring uniform transgene expression in the clones under consideration for clinical candidate selection, we compared two *in vitro* functional attributes across clones that could influence their ability to inhibit tumor growth. The first is the cell-intrinsic capacity to persist in culture in the presence or absence of CD19 expressing tumor targets in the absence of exogenous cytokine support. As seen in the figure below,

there was a meaningful difference between clones in the recovery of iNK cells after a seven day culture, with three clones demonstrating particularly favorable persistence.

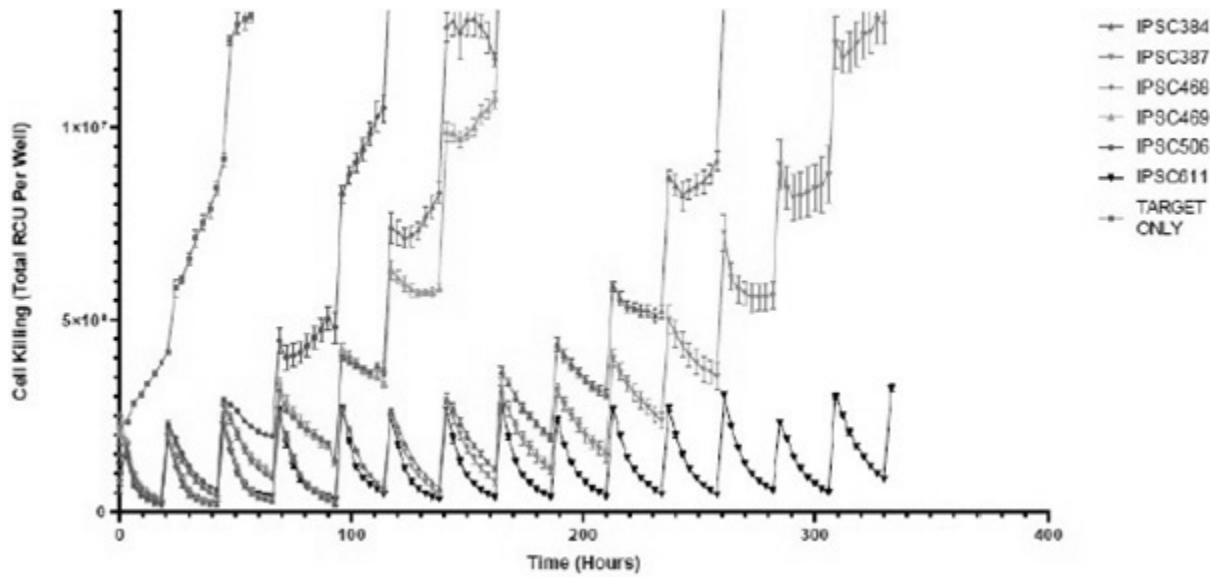


Average iNK cell number as measured by flow cytometry at the conclusion of the 7 day persistence assay. iNK cells were cultured alone or in co-culture with CD19⁺ NALM6 or REH cells at an effector to target ratio of 1:1 in the absence of any exogenous cytokine support for 7 days and then analyzed by flow cytometry. The iNK cell population was defined as live, CD45⁺, CD56⁺ cells.

Single-cell clones mediate serial killing of lymphoma cells

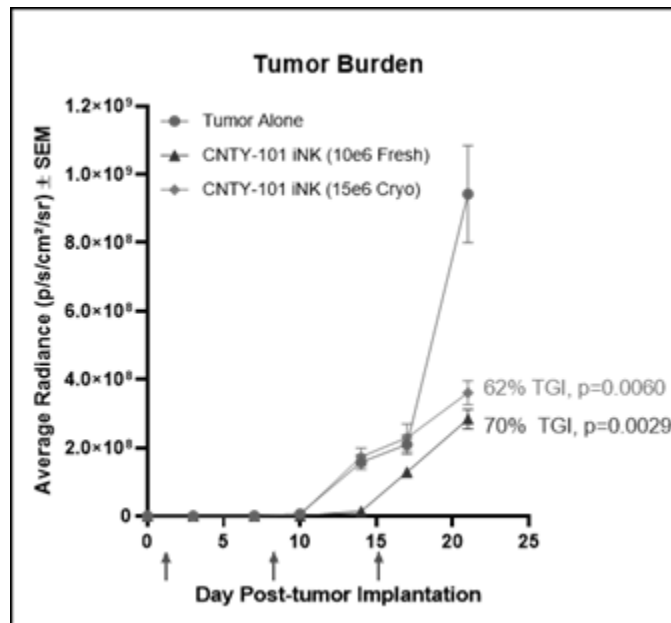
In addition to the persistence demonstrated above, for cell therapies to be effective in eliminating cancer cells, single CAR-T or CAR-NK cells need to be able to engage and kill multiple tumor cells in succession a process commonly described as serial killing. To evaluate the fitness of our CAR-iNK cells, we established a serial killing assay in which iNK cells are put through multiple rounds of killing with fresh tumor cell targets added every 24 hours. This is one of our most relevant *in vitro* assays to characterize and distinguish CAR-iNK cell clones. Our most potent clones sustain serial killing activity for over ten rounds of killing. These clones progressed to *in vivo* studies for characterization of their anti-tumor activity against human lymphoma xenografts. These *in vivo* studies determined the selection of the iPSC clone to generate the CNTY-101 clinical candidate.

Serial killing assay with single-cell iNK clones



To demonstrate the ability of our clonal CAR-iNK cells to kill lymphoma cells over multiple rounds of tumor challenge, NuclightRed labeled Nalm-6 CD19+ lymphoma cells were cocultured with iNK clones at an E:T ratio of 5:1. The plates were imaged every three hours to record the frequency of tumor cells by recording red fluorescence (Red Calibrated Unit, or RCU). Every 24 hours, new tumor cell targets were added to the wells. Differences in repeated killing are apparent with some clones having tumor serial killing for over ten rounds whereas others show loss of tumor control after five rounds of tumor killing.

Assessment of CNTY-101 inhibition of tumor growth *in vivo*

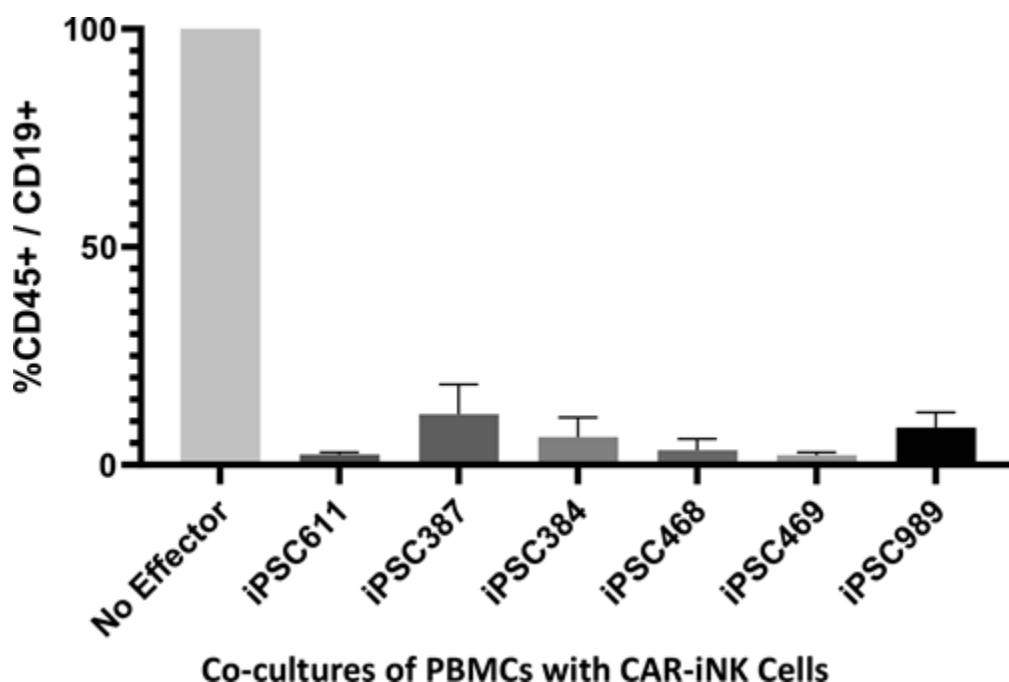


The anti-tumor activity of CNTY-101 was evaluated *in vivo* using fresh cultured CNTY-101 iNK cells or frozen cells. 1×10^5 luciferase-labeled NALM-6 lymphoma cells were administered IV on day zero. CNTY-101 iNK cells were given IV as fresh (10×10^6 cells) or cryo-preserved cells (15×10^6 cells) on Days 1, 8, and 15. Mice were imaged every 3-4 days using the IVIS SpectrumCT imager. CNTY-101 mediated significant anti-tumor growth inhibition when administered as fresh or cryo-preserved cells.

Single-cell clones eliminate CD19+ B cells

One of the key hallmarks of approved CD19 CAR-T cell therapy is the observation that patients who respond to treatment have B-cell aplasia (loss of B cells). Because normal B-cells express CD19, B-cell aplasia is expected during CD19 CAR-T cell treatment and has been used as a pharmacodynamic indicator of CAR-T cell activity. To determine whether our CD19 CAR-iNK cells eliminate normal B cells, we used B cells from four different allogeneic donors and incubated them with our top candidate iNK single cell clones. After 48 hours in culture, all iNK clones showed robust killing of B cells with complete elimination in most assays. This data indicates that B-cell aplasia should be expected during treatment of lymphoma patients. B-cell aplasia is expected to benefit our Allo-Evasion™ strategy by further reducing the chance of patients mounting a humoral anti-iNK cell antibody response.

Elimination of B Cells in Co-cultures of PBMCs with CAR-iNK Cells Derived from Single-Cell Clones



Elimination of normal B cells from whole PBMCs by our top candidate iNK single-cell clones. To evaluate B-cell killing activity *in-vitro*, CAR-iNK cells derived from six single-cell clones were co-cultured for 48 hours with PBMCs from four healthy donors. The PBMCs were labeled with cell trace violet (CTV) and cocultured with CAR-iNK clones at an effector: Target ratio of 1:1. B-cells were defined as CTV+/CD45+/CD19+ and the reduction in B-cell numbers graphed as a percentage of the total B-cells present in the co-culture conditions compared to the “No Effector” condition for each donor (set at 100%). Samples were run on BD Symphony A3 cytometer and the data is represented as average of the four PBMC donors with error bars representing standard deviation.

Our CNTY-101 clinical development program

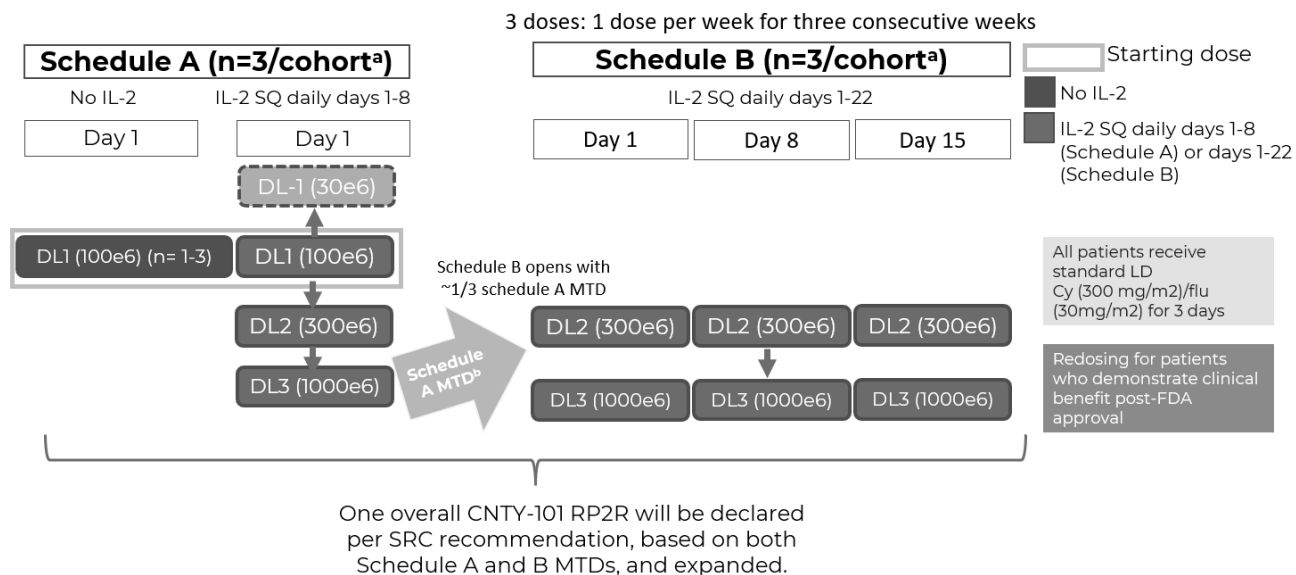
We believe the successful development of CNTY-101 will enable us to establish clinical proof of concept for our CAR- iNK cell therapy and Allo-Evasion™ technology. the clinical development of the program

We have initiated a first-in-human Phase 1 clinical trial of CNTY-101 in the United States, in relapsed and refractory CD19 positive large B-cell lymphoma, or RR NHL, patients including dose escalation and expansion portions, designed to evaluate the safety, tolerability, pharmacokinetics, persistence, efficacy, and recommended Phase 2 dose and schedule of CNTY-101. We are assessing both CD19-naïve and CD19-CAR-T treated patients who have relapsed following at least 2 prior lines of therapy. We will evaluate two dosing schedules, beginning with single dosing in Schedule A, as shown below. We will also characterize multiple doses per cycle with repeat cycles without subsequent lymphodepletion, subject to the Independent Data Review Committee and FDA review, and its potential impact on safety, persistence, and efficacy in Schedule B. The ongoing ELiPSE-1 trial is designed to evaluate preliminary safety and efficacy in patients. We intend to establish proof of concept as the study progresses through dose escalation, which will be analyzed when sufficient patient data is achieved. The CNTY-101 clinical trial will allow for benchmarking, where safety and efficacy outcomes can be compared to the available results for mono-specific CD19 autologous and allogeneic therapies that also utilize the FMC63 binder and CAR.

The primary objective of the Phase 1 clinical trial is to evaluate incidence and nature of dose-limiting toxicities within each dose level cohort and establish the recommended Phase 2 dose. The secondary objectives of the study include cell pharmacokinetics and persistence, incidence, nature, and severity of adverse events, overall response rate, complete and partial response rates, and duration of response, among other measures. Exploratory measures include evaluation of immunogenicity, correlation of antigen expression with response, and cytokine profile as a reporter of safety.

We believe CNTY-101 may provide significant treatment advantages including (i) as a result of our ability to repeat dose, the potential to enhance objective response rates, or ORRs, and the duration of response, or DoR; (ii) the potential to treat patients immediately upon diagnosis since product is available off-the-shelf; and (iii) the potential to use milder lymphodepletion regimens by reducing or eliminating the immunogenicity and alloreactivity of the administered cells, potentially providing an improved safety profile. Off the shelf availability of CNTY-101 at any clinical site, and, a potentially improved safety profile enabling outpatient use, could improve patient access. For these reasons, we believe CNTY-101, if approved by the FDA or other applicable regulatory authorities, will address substantial unmet market needs for an off-the-shelf, safe and effective cell therapy offering an improved therapeutic profile.

ELiPSE-1: First in human study of CNTY-101 Trial Schema

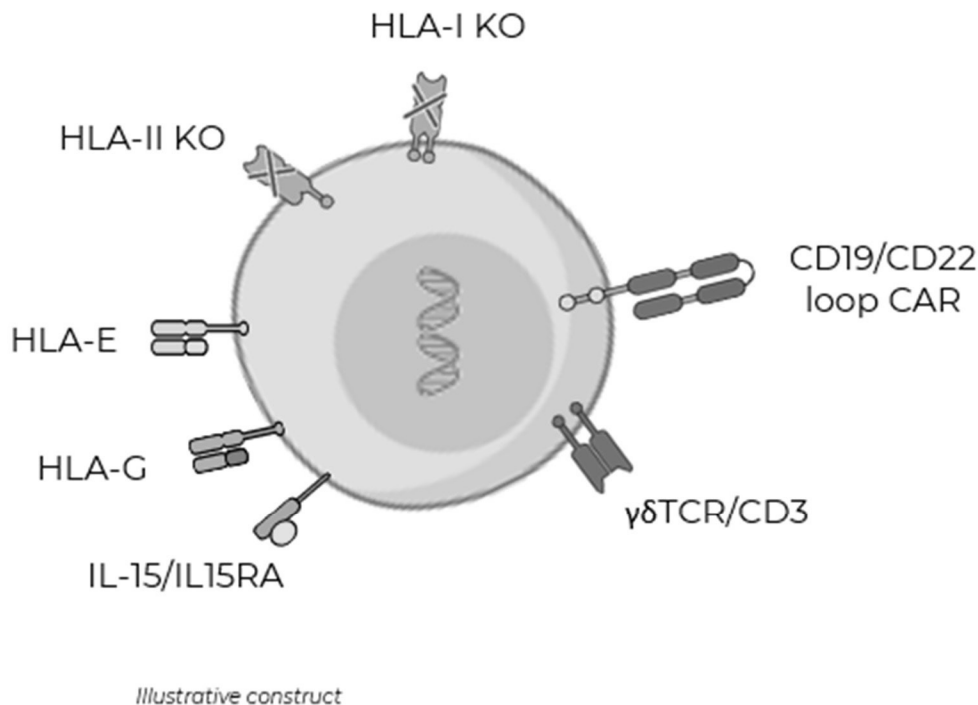


A. Escalation guided by the Bayesian Optimal Interval, or BOIN. The safety review committee reviews data and implements dosing decisions. B. After the single dose maximum tolerated dose, or MTD, has been reached or the maximum single dose has been evaluated, or earlier upon the recommendation of the Independent Data Review Committee and Sponsor decision, Schedule B will also be explored (i.e., given weekly for three weeks), starting with a fractionated dose of approximately one-third of the MTD.

CNTY-102: CAR-iT candidate targeting CD19 + CD22 for relapsed, refractory B-cell lymphoma and other B-cell malignancies

Our next-generation product candidate directed to treat B-cell malignancies is CNTY-102, an iPSC-derived Allo- Evasion™ technology enabled, CAR-iT cell therapy designed to simultaneously target two tumor antigens, CD19 and CD22. CNTY-102 will also be engineered with homeostatic cytokine support, a safety switch to be utilized for cell elimination if required clinically and possibly a PET reporter for imaging of the cells after administration to the patients. Our use of a multi-targeted CAR is intended to increase depth and durability of response by eliminating the effect of CD19 antigen loss that has been observed as a factor limiting durability of CAR-T cell therapies, as well as taking advantage of targeting CD22, an independently regulated, ubiquitous and validated B-cell target.

CNTY-102



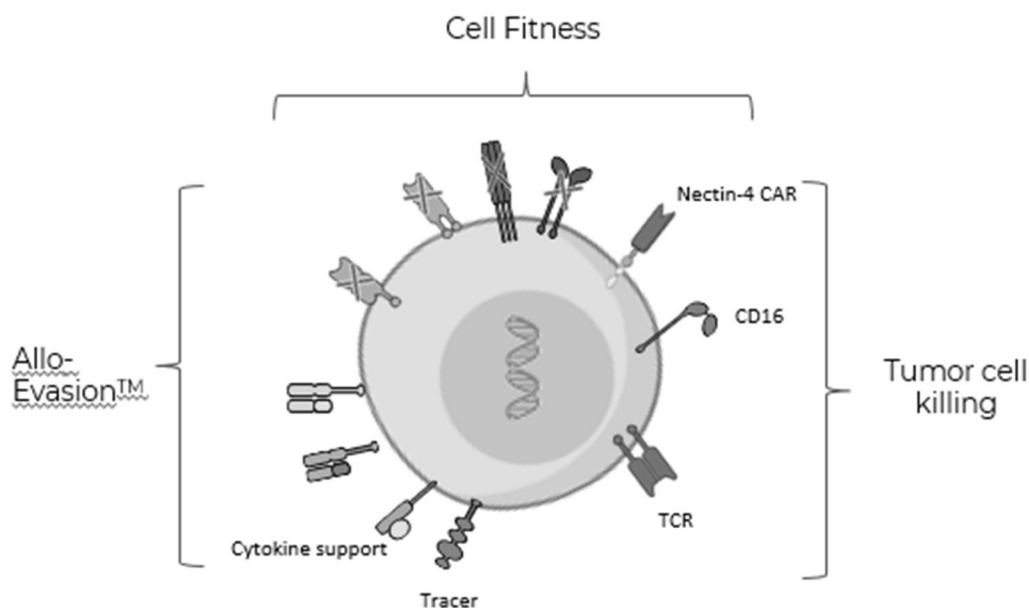
$\gamma\delta$ T cells are expected to have high proliferative capacity, persistence, and trafficking, leading to sustained anti-tumor activity. We will develop this candidate on our $\gamma\delta$ T cell therapy platform.

We anticipate preliminary clinical safety, translational (exploratory biomarker) and efficacy data will be emerging from the CNTY-101 Phase 1 trial at the time we plan to file the CNTY-102 IND, which will allow us to refine the CNTY-102 clinical design and allow for an in depth comparison. We intend to evaluate CNTY-102 in a Phase 1 clinical trial in relapsed, refractory aggressive B-cell NHL, chronic lymphocytic leukemia, or CLL, and/or B-cell acute lymphoblastic leukemia, or B-ALL. We will assess safety, tolerability, pharmacokinetics, persistence, and efficacy outcomes, with primary objectives of the Phase 1 to evaluate and compare depth and durability of response, as we believe dual tumor antigen targeting will significantly improve the efficacy profile. Additional Phase 1 objectives include determining the recommended Phase 2 clinical trial dose, schedule, and lymphodepletion conditions.

CNTY-107: Our CAR- $\gamma\delta$ T candidate targeting Nectin-4, for solid tumors expressing high levels of the target antigen

CNTY-107 is an iPSC-derived Allo- Evasion™ technology enabled, CAR- $\gamma\delta$ T cell therapy designed to address Nectin-4 positive solid tumors. CNTY-107 will also incorporate additional functionalities to enhance tumor cell killing and improve cell fitness. The Nectin cell adhesion protein 4 (Nectin-4) is overexpressed in multiple malignancies and has emerged as a possible biomarker and has been validated as target through antibody drug conjugate (ADC) approaches such as enfortumab vedotin. Nectin-4 is overexpressed in tumor types including urothelial, colorectal, breast, lung, ovarian, gastric, esophageal and pancreatic cancer.

CNTY-107



CNTY-104: Our CAR-iNK or CAR-iT multi-specific collaboration program for the treatment of acute myeloid leukemia

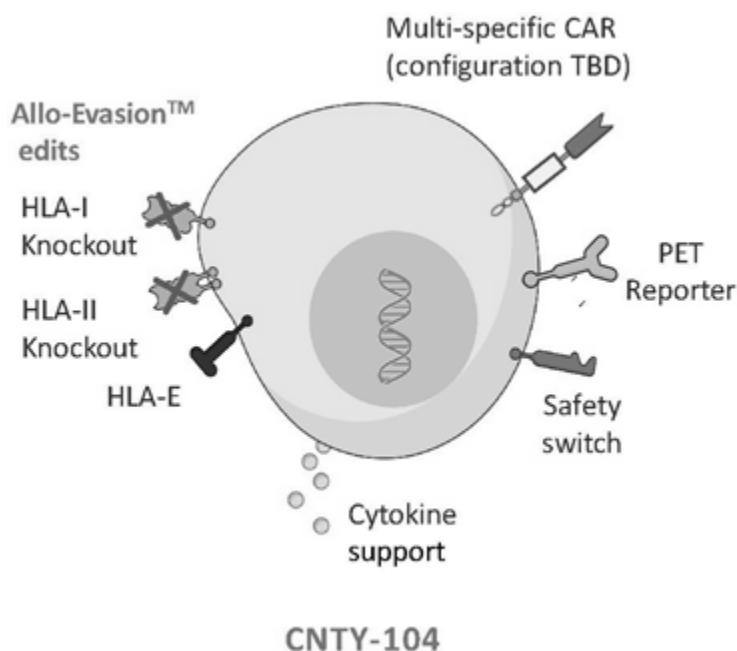
Disease background

AML is the most common form of acute leukemia, with 20,000 patients per year diagnosed in US. AML is an aggressive, heterogeneous hematopoietic malignancy characterized by genetic abnormalities in myeloid stem cells. 5-year overall survival, or OS, among patients with AML aged <60 years is ~ 35%, with 5-year OS among patients >60 years ~ 11%, reflecting a high unmet need to improve survival and quality of life for the majority of patients with AML. First line therapy includes a combination of cytarabine- and anthracycline-based regimens with allogeneic stem cell transplantation for eligible candidates, and recently approved, targeted therapies for specific mutations. Approximately 50% of patients relapse after achieving a complete remission in AML, leading to a poor prognosis. Allogeneic hematopoietic cell transplantation, or Allo-HCT, after achieving a second remission, likely offers the only possible current chance for cure. Despite numerous clinical studies, outcomes are consistently disappointing with 5-year overall survival rates of ~ 10%.

Our therapeutic approach

We are developing a multi-specific CAR-iNK or CAR-iT cell collaboration program to treat relapsed, refractory, and secondary AML in collaboration with Bristol-Myers Squibb. CNTY-104 is a CAR-iNK or CAR-iT collaboration program designed to target at least two tumor-associated antigens of relevance in AML. We are currently investigating multiple tumor targets to select the final candidates for the CNTY-104 collaboration

program. CNTY-104 will include a safety switch and possibly additional modifications including a PET reporter for imaging of the cells after administration to the patients.



Use of CAR-T cell therapies have been limited to date in myeloid malignancies due to the heterogeneity of AML cells, and, the absence of antigens that are not also expressed on normal hematopoietic stem progenitor cells. Cell therapy approaches targeting these specific antigens have often led to prolonged myeloablation, causing risk of infection and transfusion dependence in patients. As such, we are planning to create a multi-specific CAR-iNK or iT product that allows for controlled dosing and controlled persistence (e.g. enabling resting periods) to enable elimination of AML blasts while mitigating toxicities to the bone marrow. This approach may provide an improvement in treatment efficacy, tolerability, and safety. There may be an advantage to evaluate an iNK cell product, pending characterization of *in vivo* pharmacokinetics and persistence, but we will evaluate both cell platforms to engineer CNTY-104.

CNTY-106: Our CAR-iNK or CAR-iT multi-specific collaboration program for the treatment of multiple myeloma

Disease background

Multiple myeloma is the second most common hematological malignancy, accounting for approximately 10 percent of all blood cancers. The five-year survival rate has improved with the introduction of targeted therapies, combination regimens and more recently antibody drug conjugates and cell therapies but remains incurable. An estimated 35,000 new cases are diagnosed in the U.S. annually, with approximately 12,500 deaths. The 5-year survival rate for patients under 45 years of age at diagnosis is approximately 77 percent.

We are developing a multi-specific CAR-iNK or CAR-iT cell product candidate to treat relapsed, refractory multiple myeloma collaboration with Bristol-Myers Squibb. CNTY-106 is a CAR-iNK or CAR-iT collaboration program to target at least two tumor-associated antigens of relevance in multiple myeloma.

Discovery platform

In addition to our named programs, we are actively engaged in a number of earlier stage discovery programs where we believe our iPSC-derived allogeneic cell therapy platform may provide differentiated therapeutic

benefits. These discovery stage initiatives are focused on several solid tumor indications including bladder cancer and renal cell carcinoma. For these indications we plan to use multi-specific CARs and explore the use of both iNK and iT cells to identify the best cell platform to build the product candidate.

We have initiated multiple VHH antibody campaigns to identify binders to build the CAR constructs for the prioritized tumor indications. These campaigns are at different stages of development and include targets for targets for renal cell carcinoma and other solid tumors and hematological malignancies. Our goal is to do side by side comparisons of the different CARs to select the final CAR constructs for the product candidates. We intend to evaluate the use of engineered macrophages and dendritic cells in the future as potential anti-cancer cell therapies. We believe the function of these immune cells may enable both standalone use as well as their inclusion in potent effector cell cocktails where the complementary engagement of the different immune cells reinforces and enhance overall therapeutic efficacy against different type of tumor malignancies.

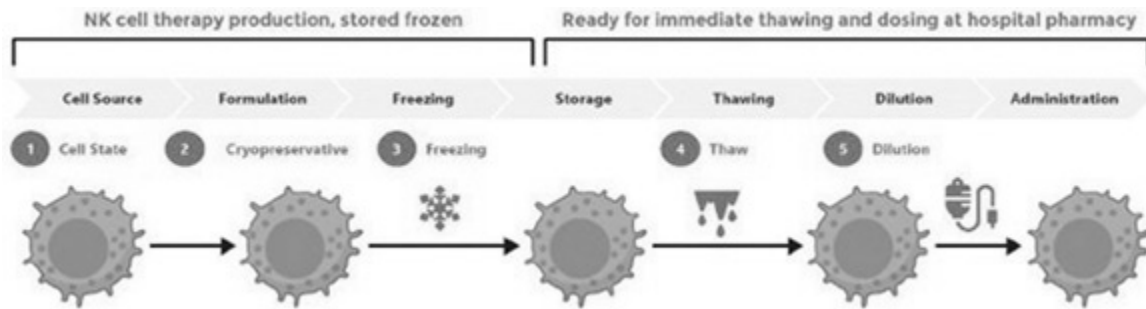
Manufacturing

We believe that our iPSC-derived NK cells and T cells afford us a significant opportunity to advance multiplex gene-edited cell therapies that can be produced at substantially lower cost and accessible by a much larger patient population as compared to other donor-derived and autologous cell therapy approaches. To capitalize on these advantages, we believe it is imperative to develop an intimate understanding of the relevant cell types, the processes used to manufacture these cells, and the analytical methods required to accurately and reliably measure critical product attributes. We believe this understanding will enable us to produce safe and efficacious products, implement process and product changes with greater efficiency and accelerate the clinical development of commercializable products. In addition, we intend to develop a significant depth of expertise related to scale manufacturing, which we believe is essential to enable cell expansion, harvest and final container filling, along with cryopreservation, at a significantly reduced per dose cost. We have constructed our manufacturing strategy with the intent of achieving these objectives.

We believe that our relationship with FCDI and its role in the manufacture of our initial product candidates has provided valuable know-how that accelerated development of our proprietary methods to generate functional iPSC-derived iNK cells. We believe that our optimized iPSC differentiation methods are scalable and compatible with efficient manufacturing processes. Our process development group is responsible for overall management of process optimization efforts and we have contracted with FCDI to provide us with process development services on an ongoing basis.

Current activities with FCDI are focused on enhancements to NK cell production. As the protocols for cryopreservation of NK cells are not as well established as the protocols for T cell freezing and storage, we believe that addressing the key determinants of cryopreservation is of particular relevance to the success of our more advanced therapeutic programs. The ability of NK cells to withstand cryopreservation depends not only on the freezing step itself, but on multiple factors in the entire manufacturing process both preceding and following freezing, including the thawing process and post-thaw handling prior to patient administration. As such, all factors involved in the supply chain, from initial cell engineering to patient administration, are being addressed to characterize the impact of cryopreservation on NK cells, especially its impact on yield, activity, stability and consistency. We have invested significant resources to optimize our manufacturing process and continue to iteratively invest in this area. We are also committing additional resources to ensure that adequate infrastructure and expertise is available at clinical sites regarding handling and treatment preparation.

Effective cryopreservation strategies must consider all elements of the supply chain



We are sourcing clinical supply of CNTY-101 from FCDI. FCDI currently maintains a cGMP compliant manufacturing facility in Madison, Wisconsin and our audit of the facility confirmed its Phase 1 readiness. We also intend to source clinical trial supply for our other iNK product candidates, and we will have the option to source NK cell therapies to be sold commercially, if approved, from FCDI.

At the same time, we have constructed of our own 53,000 square foot cell therapy manufacturing facility in Branchburg, New Jersey, which is now operational. While we intend to use this facility as the primary manufacturing site for CAR-iT cell therapies, we have designed the facility to be a flexible, multi-product facility, capable of producing any immune cell type, and thereby serving as an alternative manufacturing site for our CAR-iNK cell therapies as well.

We believe the development of in-house manufacturing will enable us to analyze, learn and adapt more rapidly and increase control of development and manufacturing timelines for efficient clinical development of our product candidates. Through this enhanced control and investment in our process and analytical development capabilities, we believe we will gain a deeper understanding of our critical product attributes and better understand the factors that affect product quality. We also intend to develop expertise in scale-up technologies to enable optimal manufacturing scale for our product candidates, which will reduce cost of goods and improve patient access.

Licensing, partnerships and collaborations

Fujifilm Cellular Dynamics, Inc.

We are party to an exclusive license with FCDI, dated September 18, 2018, or, as amended, the Differentiation License, pursuant to which we have licensed from FCDI certain patents and know-how related to differentiation of iPSC cells into immune-effector cells in the field of cancer immunotherapeutics. We are also party to a non-exclusive license with FCDI, also dated September 18, 2018, or, as amended, the Reprogramming License, pursuant to which we have licensed from FCDI certain patents and know-how related to the reprogramming of human somatic cells to iPSCs in the field of cancer immunotherapeutics. On October 21, 2019, we entered into a Master Collaboration Agreement with FCDI pursuant to which we agreed to fund research and development work at FCDI pursuant to a research plan, or, as amended, the FCDI Collaboration Agreement. On March 23, 2021, we entered into a Manufacturing and Supply Agreement with FCDI, or the Manufacturing Agreement, pursuant to which FCDI will provide certain agreed upon technology transfer, process development, analytical testing and cGMP manufacturing services to us. On January 7, 2022, we entered into a letter agreement with FCDI, which amends each of the agreements in relation to our collaboration with Bristol-Myers Squibb.

Differentiation License Agreement

Under the Differentiation License, FCDI granted us an exclusive, fully paid-up, sublicensable, worldwide, excluding Japan, license under certain patent rights and know-how related to human iPSC to exploit cancer

immunotherapy products consisting of cells that are or are modifications of NK cells, T cells, dendritic cells and macrophages derived from human iPSC, or FCDI Licensed Products. In return, we granted FCDI an exclusive, fully paid-up, sublicensable license under certain patents and know-how controlled by us to exploit FCDI Licensed Products for any cancer immunotherapy use in Japan or, with respect to any abandoned indication, worldwide, and a non-exclusive license to manufacture the FCDI Licensed Products for any cancer immunotherapy use worldwide until the termination of the Differentiation License. We also granted to FCDI a non-exclusive, sublicensable, worldwide license under certain manufacturing know-how developed by us under the Differentiation License or FCDI Collaboration Agreement for manufacturing and process development activities outside of the field of cancer immunotherapy for cells other than NK cells, T cells, dendritic cells and macrophages derived from human iPSC until the termination of the Differentiation License.

Under the Differentiation License, FCDI has an option, executable once a product candidate meets its primary endpoint(s) in a Phase 2 clinical trial, to exploit FCDI Licensed Products in Japan or, with respect to any abandoned indication, worldwide. If FCDI does not exercise its option, we will have the right to exploit FCDI Licensed Products in Japan, and we and FCDI will amend the Differentiation License as necessary to permit such exploitation. We also issued shares of common stock to FCDI as consideration under the Differentiation License.

The Differentiation License expires upon the expiration of the last-to-expire patent licensed thereunder, which is currently expected to expire in 2036. Either party may terminate the Differentiation License upon the other party's breach of any material obligation, subject to a 60-day notice and cure period, or in the event of the other party's bankruptcy, if not dispensed or otherwise disposed within 60 days. We may terminate the Differentiation License in its entirety or on an indication-by-indication basis, a product-by-product basis or country-by-country basis, for convenience upon 90 days' written notice. In addition, FCDI may terminate the Differentiation License if we fail to achieve certain development milestones within four years of successful completion of the first proof of concept clinical trial for an FCDI Licensed Product in the United States or European Union, subject to an additional extension of up to one year in limited circumstances. FCDI may also terminate the Differentiation License upon written notice in the event of termination of Reprogramming License.

The Differentiation License also contains customary representations and warranties, confidentiality, insurance and indemnification provisions.

Reprogramming License Agreement

Under the Reprogramming License, FCDI granted us a non-exclusive, worldwide, excluding Japan, license under certain patent rights and know-how related to cell reprogramming of human cells to iPSCs to exploit FCDI Licensed Products within the field of cancer immunotherapeutic. Included within the rights granted to us under such license are rights sublicensed to us under certain patents owned by the Wisconsin Alumni Research Foundation, or WARF, relating to the "Thompson Factors" for reprogramming human cells to iPSCs, pursuant to a license agreement between FCDI and WARF, or the WARF License. In return, we granted FCDI a non-exclusive, fully paid up, sublicensable license to manufacture or practice developments made by us in Japan and to practice developments made by us to manufacture FCDI Licensed Products worldwide until the termination of the Reprogramming License. We also granted to FCDI a non-exclusive, sublicensable, worldwide license under certain developments made by us under the Reprogramming License to make, have made, use, have used, research and develop iPSCs for activities outside of the field of cancer immunotherapy, so long as such rights are not used in conjunction with any other technology to differentiate iPSCs into NK cells, T cells, macrophages, or dendritic cells.

Under the Reprogramming License, we agreed to pay FCDI low single-digit percentage royalty payments on net sales of FCDI Licensed Products, as required by the WARF License, until the expiration of the last-to-expire patent licensed thereunder. We also agreed to pay certain milestone payments to FCDI as required by the WARF License upon the achievement of certain development and commercial milestones up to an aggregate of \$6 million per FCDI Licensed Product.

The Reprogramming License expires upon the expiration of the last-to-expire patent licensed thereunder, which is currently expected to expire in 2034. Either party may terminate the Reprogramming License upon the other party's breach of a material obligation, subject to a 60-day notice and cure period, or in the event of the other party's bankruptcy, if not dispensed or otherwise disposed within 60 days. We may terminate the Reprogramming License for convenience upon 90 days' notice in its entirety or on a product-by-product or country-by-country basis. FCDI may terminate the Reprogramming License if we fail to achieve certain development milestones within four years of successful completion of the first proof of concept clinical trial for an FCDI Licensed Product in the United States or European Union, subject to an additional extension of up to one year in limited circumstances. FCDI may also terminate the Reprogramming License upon written notice in the event of termination of the Differentiation License.

The Reprogramming License also contains customary representations and warranties, confidentiality, insurance and indemnification provisions.

FCDI Collaboration Agreement

Under the FCDI Collaboration Agreement, we established a collaborative relationship under which FCDI agreed to render certain services to us for the development and manufacture iPSC-derived cells in accordance with a research plan and approved budget funded by us. For the first three years of the term of the FCDI Collaboration Agreement, we agreed to pay FCDI a minimum of \$2.5 million per year. Under the FCDI Collaboration Agreement, with certain exceptions, we have ownership rights to the deliverables made under the collaboration, including any intellectual property rights therein. Such exceptions include, among other things, deliverables that are cells obtained or created by changing the state of a cell to a state of pluripotency using methods or materials covered by the licensed patents, or Reprogrammed iPS Cells, or any compositions or materials derived from the use of Reprogrammed iPS Cells, produced by the use of Reprogrammed iPS Cells or which incorporate wholly or partially Reprogrammed iPS Cells, which, in each case, will be owned by FCDI, unless directly or indirectly derived from or made from the cell lines selected by us pursuant to the terms of the FCDI Collaboration Agreement.

The FCDI Collaboration Agreement expires upon the termination of the Reprogramming License. Either party may terminate the FCDI Collaboration Agreement upon the other party's material breach, subject to a 30-day notice and cure period. We may terminate the FCDI Collaboration Agreement for convenience by providing FCDI 60-days' written notice.

The FCDI Collaboration Agreement also contains customary representations and warranties, confidentiality and indemnification provisions.

Letter Agreement

Under the letter agreement, which amends certain terms of each of the FCDI Agreements, including such amendments that (i) amend the definition of Territory under each of the FCDI Agreements, for purposes of the sublicenses under the FCDI Agreements pursuant to the Company's Research Collaboration and License Agreement with Bristol-Myers Squibb dated January 7, 2022, or the Collaboration Agreement, includes Japan, (ii) amends the licenses granted to the Company and its affiliates under the FCDI Agreements such that the rights are sublicensable to Bristol-Myers Squibb, including with respect to Japan and (iii) the intellectual property developed under the Bristol-Myers Squibb collaboration is not subject to grant-back and option provisions under the Reprogramming License (iv) waives any right of FCDI to manufacture products developed under the Collaboration Agreement.

Pursuant to the Letter Agreement, and in consideration for amending the FCDI Agreements, we paid to FCDI (i) an upfront payment of \$10 million, and will pay (ii) a percentage of any milestone payments received by us under the Collaboration Agreement in respect of achievement of development or regulatory milestones specific to Japan, and (iii) a percentage of all royalties received by us under the Collaboration Agreement in respect of sales of products in Japan.

Manufacturing Agreement

Under the Manufacturing Agreement, FCDI will perform certain agreed upon technology transfer, process development, analytical testing, and cGMP manufacturing services for us with respect to clinical supply of our product candidates as agreed to in future work orders. The Manufacturing Agreement contains certain exclusivity provisions, which remain effective until the fifth anniversary of the Manufacturing Agreement, including that FCDI will be our exclusive clinical supplier for the first NK cell product candidate for which we submit an IND and that FCDI will have the option to be our exclusive clinical supplier for certain of our next three or four product candidates for which we may submit an IND, depending on whether they are NK cell product candidates or T cell product candidates. Subject to certain conditions, FCDI may also have the right to be the exclusive clinical supplier for the first product candidate for which we submit an IND after the fifth anniversary of the Manufacturing Agreement.

Either party may terminate the Manufacturing Agreement upon the other party's material breach, subject to a 30-day notice and cure period, or in the event that the activities to be performed under the Manufacturing Agreement are unable to be performed for scientific or technical reasons and the parties are unable to resolve such issue within 60 days. We may terminate the Manufacturing Agreement for convenience after March 23, 2026 by providing FCDI 60-days' written notice.

Bayer HealthCare LLC

Option Agreement

In June 2019, we entered into an option agreement with Bayer, or the Option Agreement, which was subsequently amended and restated in February 2021, pursuant to which Bayer was granted certain bidding rights relating to the potential transfer of rights with respect to certain product candidates being researched and developed by us which are comprised of allogeneic iPSC-derived natural killer cells, macrophages or dendritic cells, which we refer to as the Research Products. For clarity, T cell programs are excluded from the Bayer Option Agreement Research Products. Under the Option Agreement, Bayer was granted a right of first refusal, or ROFR, to submit bids for the transfer or license of rights to research, develop and/or commercialize certain Research Products, which we refer to as the Research Product Rights.. While CNTY-101 is no longer included in the Bayer option rights, any other wholly owned product candidate comprised of iNK cells that we develop in the future is subject to the terms of the Option Agreement. Bayer's ROFR is only exercisable with respect to up to four Research Products and the right terminates upon our tenth IND submission. Subject to certain exceptions, Bayer may only exercise these option rights in a non-sequential and alternating manner, and such rights are subject to additional limitations.

In the event that Bayer exercises its ROFR right, we will provide Bayer with our current, minimum offer terms with respect to the relevant Research Product Rights, or the Minimum Offer Terms, as determined by our Board (excluding any director appointed by Bayer), which will include (i) the minimum upfront cash proceeds to be received by us for the Research Product Rights and (ii) any other applicable licensing and financial terms. If Bayer's bid does not meet the Minimum Offer Terms, Bayer's ROFR rights with respect to that Research Product terminate except that Bayer will retain topping rights for future third party bids for that Research Product. If Bayer's bid meets the Minimum Offer Terms, we can accept the bid or seek a third party valuation to determine the fair market value of the Research Product Rights and Bayer will have the opportunity to match the third party valuation. If Bayer does not match the third party valuation, Bayer's rights with respect to that Research Product terminate except that Bayer will retain topping rights for future third party bids for that Research Product that are less than the third party valuation. The Option Agreement also contains provisions regarding our receipt of an unsolicited bid for certain Research Product Rights prior to an IND submission for a Research Product under which Bayer will have the option to submit a competing bid or relinquish its rights with respect to the transfer of the applicable Research Product in connection with the unsolicited bid.

The Option Agreement terminates upon the earlier of (i) Bayer and its affiliates ceasing to hold any of our capital stock or (ii) a change of control of us, as defined therein. The Option Agreement also contains customary representations and warranties and confidentiality provisions.

Bristol-Myers Squibb

On January 7, 2022, we entered into the Collaboration Agreement with Bristol-Myers Squibb to collaborate on the research, development and commercialization of iNK and iT cell programs for hematologic malignancies and solid tumors, each a Collaboration Program, and each product candidate developed within such Collaboration Program, a Development Candidate.

Pursuant to the Collaboration Agreement, we and Bristol-Myers Squibb will initially collaborate on two Collaboration Programs and Bristol-Myers Squibb has the option to add up to two additional Collaboration Programs, for an additional fee. The initial two Collaboration Programs are focused on AML and multiple myeloma, respectively. The two additional Collaboration Programs that Bristol-Myers Squibb may elect to add to the collaboration will focus on targets chosen from a set of reserved targets or other targets selected by Bristol-Myers Squibb, which can be nominated subject to certain conditions agreed with us and outlined in the Collaboration Agreement.

Under the Collaboration Agreement, we are responsible for generating Development Candidates for each Collaboration Program with a goal of producing Development Candidates that meet pre-specified criteria. Bristol-Myers Squibb has the option, exercisable for a specified period of time after the Development Candidate for each Collaboration Program is deemed to meet the applicable criteria, to elect to exclusively license the Development Candidates created in each Collaboration Program for pre-clinical development, clinical development and commercialization on a worldwide basis each a License Option. Following Bristol-Myers Squibb's exercise of the License Option with respect to a Collaboration Program, we will be responsible for performing IND-enabling studies, supporting Bristol-Myers Squibb's preparation and submission of an IND and manufacturing of clinical supplies until completion of a proof of concept clinical trial for the relevant Development Candidates, in each case at pre-agreed rates. Bristol-Myers Squibb will be responsible for all regulatory, clinical, manufacturing (after the proof of concept clinical trial) and commercialization activities for such Development Candidates worldwide.

We have the option to co-promote with Bristol-Myers Squibb Development Candidates generated from the initial AML Collaboration Program and, if Bristol-Myers Squibb elects to expand to a fourth Collaboration Program, Development Candidates generated from the fourth Collaboration Program.

Under the terms of the Collaboration Agreement, Bristol-Myers Squibb made a non-refundable, upfront cash payment of \$100 million and will pay an exercise fee upon the exercise of the License Option with respect to a Collaboration Program, each such Collaboration Program, a Licensed Program and product candidates developed under a Licensed Program, Licensed Products. With respect to each Licensed Program, Bristol-Myers Squibb will pay up to \$235 million in milestone payments upon the first achievement of certain development and regulatory milestones within such Licensed Program. In addition, Bristol-Myers Squibb will pay up to \$500 million per Licensed Product in net sales-based milestone payments.

Bristol-Myers Squibb will also pay us tiered royalties per Licensed Product as a percentage of net sales in the high-single digits to low-teens, subject to reduction for biosimilar competition, compulsory licensing and certain third party licenses costs. If we exercise our co-promote option, such royalty percentage will be increased to low-teens to high-teens in respect of the sales of the co-promoted Licensed Products in the United States. The royalty term shall terminate on a Licensed Product-by-Licensed Product and country-by-country basis on the latest of (i) the twelve (12) year anniversary of the first commercial sale of such Licensed Product in such country, (ii) the expiration of any regulatory exclusivity period that covers such Licensed Product in such country, and (iii) the expiration of the last-to-expire licensed patent of the Company or a jointly owned patent that covers such the Licensed Product in such country. After expiration of the applicable

royalty term for a Licensed Product in a country, all licenses granted by the Company to Bristol-Myers Squibb for such Licensed Product in such country will be fully paid-up, royalty-free, perpetual and irrevocable.

In connection with the Collaboration Agreement Bristol-Myers Squibb purchased 2,160,760 shares of the our common stock at a price per share of \$23.14, for an aggregate purchase price of \$50 million.

iCELL Inc.

On March 20, 2020, we entered into an exclusive sublicense, or the iCELL Sublicense, with iCELL Inc., or iCELL, for certain patents related to an immune function reconstruction method using multipotent stem cells and the method for producing antigen specific T-cells, in each case, to research, develop and commercialize products in the United States, France, Germany, Italy, Liechtenstein, the Netherlands, Switzerland and the UK and any other countries where valid claims exist. Additionally, we received a non-exclusive license to such rights in Japan. The rights sublicensed to us under the iCELL Sublicense were licensed to iCELL by the University of Tokyo, or UTokyo, pursuant to an exclusive license agreement, or the UTokyo License. iCELL reserved for itself and for UTokyo an irrevocable, nonexclusive, royalty-free license to make and use certain non-public information for their own internal educational and research activities.

The initial term of the sublicense expires on the later of (i) March 31, 2027, or (ii) the expiration of the last-to-expire valid claim covering a licensed product, which is currently expected to expire in 2033. iCELL may terminate the agreement with 30 days' notice if we have failed to make a payment within 60 days of such payment becoming due and we do not cure such breach within 30 days of written notice. We may terminate the agreement upon 90 days' written notice if any third party brings a claim against us related to the licensed patents or technology and such claim is not settled within 90 days.

Pursuant to the iCELL Sublicense, we paid an upfront license issue fee in the low six-figures and we agreed to make low single-digit percentage royalty payments until the last-to-expire valid claim under the licensed patents to iCELL on certain net sales amounts of the products developed under the iCELL Sublicense, as well as commercial milestone payments on a country-by-country basis based on certain net sales amounts related to products developed under the iCELL Sublicense in the aggregate of \$70 million. We also agreed to make certain milestone payments to iCELL upon the achievement of certain developmental and regulatory milestones in the aggregate of \$4.25 million. Upon the termination of the UTokyo License, iCELL will use good faith efforts to assist us in exercising any rights available to us under the UTokyo License to become a direct licensee of UTokyo. The iCELL Sublicense also contains customary representation and warranties, confidentiality, insurance, audit, indemnification and miscellaneous provisions.

University of Toronto and McMaster University

On June 9, 2020, we entered into an asset purchase agreement by and among Empirica, our wholly-owned subsidiary Century Therapeutics Canada ULC, or Century Canada and us pursuant to which we purchased certain assets of Empirica, including a license agreement, or the Empirica License, dated January 22, 2019, by and among the Governing Council of the University of Toronto, or the Council, the McMaster University, or, together with the Council, the Toronto Universities, and Empirica. Under the Empirica License, we received an exclusive, non-transferable, sublicensable, worldwide license under certain patents and antibody sequences and related intellectual property rights and know-how to, among other things, reproduce, manufacture and commercialize certain CD-133 related antibody and antibody sequence-derived technology, including but not limited to BiTE and bi-Specific or engineered T-Cells, including but not limited to CAR-Ts. The Toronto Universities reserve a royalty-free, non-exclusive, perpetual, irrevocable license to use such technology for non-commercial research, educational and administrative purposes.

The Empirica License expires upon the expiration of the last-to-expire valid claim covering the antibody and antibody-derived technology licensed under the agreement, which, if issued, is expected to expire in 2037. The Toronto Universities may immediately terminate the agreement upon certain insolvency events or upon

our material breach with 30 days' prior written notice and cure period. We may terminate the agreement for convenience upon 30 days' written notice.

Pursuant to the Empirica License, we are required to make aggregate milestone payments of \$18 million to the Toronto Universities upon the achievement of regulatory approval for certain products developed pursuant to the Empirica License in the United States, European Union and Japan until the expiration of the last-to-expire valid claim covering the antibody and antibody-derived technology licensed under the agreement. We are also required to make royalty payments to the Toronto Universities in an amount equal to a low single-digit percentage of annual net sales of any product commercialized utilizing technology licensed under the Empirica License. We are also required to pay the Toronto Institutions 50% of all non-royalty payments from sublicenses up to certain maximum amounts and 50% of royalty payments from sublicenses up to a maximum low single-digit percentage. The Empirica License contains customary representations and warranties, confidentiality, insurance, audit and indemnification provisions.

Inscripta

In January 2019, we entered into a non-exclusive license agreement with Inscripta, Inc. Under the license agreement, we obtained a non-exclusive, worldwide, royalty-free, irrevocable license to a patent portfolio covering the composition, production and use of CRISPR-MAD7, a novel gene-editing CRISPR endonuclease from the *Eubacterium rectale* genome. The license agreement does not contain any payment terms; thus no payments have been made, or will be made, to Inscripta under the license agreement. The licensed intellectual property includes two issued U.S. patents and any pending applications claiming priority therefrom. Our license covers the use of CRISPR-MAD7 to perform research and development in both academic and commercial setting and use of MAD7 to perform commercial services, provided that such use may not include the (i) sale or resale of MAD7, including as part of a therapeutic product, (ii) continued use of MAD7 in a commercial manufacturing process or (iii) use of MAD7 in the editing of human embryos. Such license will expire upon the expiration of the last valid claim under the licensed patents, which is currently expected to expire in 2037. These licensed issued patents and any licensed patents that may issue from these pending patent applications will expire in 2037, without giving effect to any patent term adjustment or extension.

Intellectual property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance our intellectual property, proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, enforcing and defending patent rights, whether developed internally or licensed from third parties.

We do not own any issued patents covering our product candidates, platforms or technology and our patent portfolio is currently comprised only of patent applications. We have filed patent applications related to our product candidates CNTY-101, CNTY-102 and CNTY-107, but have not yet filed any patent applications on our other product candidates. We have also filed patent applications relating to our T-cell platform related to compositions and methods for generating alpha-beta and gamma delta T-cells from iPSCs. Additionally, we have filed a patent application on gene transfer vectors and methods of engineering iPSCs. We have sought patent protection in the United States related to our CNTY-101 product candidate, as well as other iPSC-derived engineered CAR cells comprising certain transgene insertions and deletions, including our proprietary Allo-Evasion™ technology. This portfolio covers compositions of programmed cellular immunotherapies, our proprietary Allo-Evasion™ technology and our platform for industrial scale iPSC engineering and differentiation. The portfolio also includes technology for a universal CAR cell platform and a novel safety switch. With regard to such United States provisional patent applications, if we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. Such applications may not result in issued patents and, even if patents do issue, such patents may not be in a form that will provide us with meaningful protection for our product candidates. We also rely on trade secrets that

may be important to the development of our business, but which may be difficult to protect and provide us with only limited protection.

We expect to file additional patent applications in support of current and new clinical candidates as well as new platform and core technologies. Our commercial success will depend in part on obtaining, maintaining, protecting and enforcing patent protection and trade secret protection of our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending such patents against third-party challenges and operating without infringing, violating or misappropriating the intellectual property or proprietary rights of others. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. 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 patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes. For this and more comprehensive risks related to our intellectual property, please see “Risk factors—Risks related to our intellectual property.”

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, including the United States, the patent term is generally 20 years from the earliest date of filing a non-provisional or Patent Cooperation Treaty, or PCT patent application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any issued patents we may obtain in any jurisdiction where such patent term extensions are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see “Risk factors—Risks related to our intellectual property.”

In some instances, we submit patent applications directly with the USPTO as provisional patent applications. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date to claim priority to the provisional application filing date. With regard to such United States provisional patent applications, if we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

We will file U.S. non-provisional applications and PCT applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding

patentability opinion for some or all of the claims filed in the application, which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national- phase applications. At the end of the period of two and a half years from the earliest priority date of the PCT application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Office. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing.

For all patent applications, we determine claiming strategy on a case-by-case basis. We seek to file patents containing claims for protection of all useful applications of our proprietary technologies and any product candidates, as well as all new applications and/or uses we discover for existing technologies and product candidates, assuming these are strategically valuable. We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims to pursue maximum coverage and value for our processes, and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

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

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing, violating or misappropriating the intellectual property or proprietary rights of third parties. Third-party patents could require us to alter our development or commercial strategies, or our product candidates or processes, obtain licenses, which may not be available on commercially reasonable terms, or at all, or cease certain activities. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. Further, our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our product candidates may have a material adverse impact on us. For more information, see “Risk Factors—Risks Related to Intellectual Property.”

In addition to patent protection, we also rely on trade secrets, know-how, other proprietary information and/or continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual’s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee’s use of our confidential information are our exclusive property. However, such confidentiality agreements and invention

assignment agreements can be breached and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions. For more information regarding the risks related to our intellectual property, see “Risk factors—Risks related to our intellectual property.”

Intellectual property relating to iPSC technology

We have licensed from FCDI a portfolio of six patent families including issued patents and pending applications broadly applicable to the reprogramming of somatic cells. Our license is non-exclusive within the field of cancer immunotherapeutics in the worldwide territory outside of Japan. This portfolio covers various aspects of the generation of human iPSCs from somatic cells and, as of May 31, 2021, includes 12 issued U.S. patents claiming methods and compositions used in the reprogramming of human somatic cells to iPSCs. Specifically, the portfolio includes patents with claims for producing human iPSCs from hematopoietic progenitor cells using episomal genetic vectors and includes claims for doing the reprogramming under feeder free conditions. The portfolio also includes a composition of matter patent issued in the United States covering an Epstein-Barr Virus, or EBV, reprogramming vector containing genes for certain reprogramming factors. These issued patents and any patents that may issue from these pending patent applications will expire on dates ranging from 2029 to 2034, without giving effect to any patent term adjustment or extension.

Included within the license is a sublicense under certain patents, which are directed to compositions and methods of using and making iPSCs, owned by WARF relating to the so-called “Thompson Factors” for reprogramming human cells to iPSCs, The issued United States patents in this portfolio will expire on dates ranging from 2028 to 2029, without giving effect to any patent term adjustment or extension.

Given that the rights granted to us under these patents are non-exclusive, third parties may obtain licenses to these patents and related technology to compete with us. For more information, see “Risk Factors—Risks related to commercialization of our product candidates—We face significant competition, and if our competitors develop product candidates more rapidly than we do or their product candidates are more effective, our ability to develop and successfully commercialize products may be adversely affected.”

Intellectual property relating to genetic engineering

In January 2019, we entered into a non-exclusive license agreement with Inscripta, Inc. Under the license agreement, we obtained a non-exclusive, royalty-free, irrevocable license to a patent portfolio covering the composition, production and use of CRISPR-MAD7, a novel gene-editing CRISPR endonuclease from the *Eubacterium rectale* genome. The intellectual property includes two issued U.S. patents and any pending applications claiming priority therefrom. Our license covers the making and using of CRISPR-MAD7 for editing iPSCs, making master engineered iPSC lines and using master engineered iPSC lines to manufacture human therapeutic products. These issued patents and any patents that may issue from these pending patent applications will expire in 2037, without giving effect to any patent term adjustment or extension.

Given that the rights granted to us under these patents are non-exclusive, third parties may obtain licenses to these patents and related technology to compete with us. For more information, see “Risk Factors—Risks related to commercialization of our product candidates—We face significant competition, and if our competitors develop product candidates more rapidly than we do or their product candidates are more effective, our ability to develop and successfully commercialize products may be adversely affected.”

Intellectual property relating to the differentiation of hematopoietic cells

We have licensed from FCDI a portfolio of six patent families regarding methods of differentiating iPSC cells including issued patents and pending patent applications broadly applicable to the differentiation of iPSC cells, the last of which is currently expected to expire in 2036. Our license is exclusive to exploit cancer

immunotherapeutic products consisting of cells that are or are modifications of NK cells, T cells, dendritic cells and macrophages derived from human iPSCs. This portfolio covers various aspects of the generation of hematopoietic precursor and immune effector cells from iPSCs and, as of May 31, 2021, includes five issued U.S. patents claiming methods for the differentiation of human iPSCs to hematopoietic precursor cells and further differentiation into immune effector cells. Specifically, the portfolio includes patents with claims for producing hematopoietic precursor cells from iPSCs using a multi-step process involving certain defined media. These issued patents and any patents that may issue from these pending patent applications will expire on dates ranging from 2030 to 2036, without giving effect to any patent term adjustment or extension.

Intellectual property relating to engineered iPSCs and derivative cells

Currently, we own ten pending utility patent applications and eight pending provisional patent applications covering our engineered iPSC cells, cell differentiation technology, compositions of engineered cellular immunotherapies, and gene transfer vectors and methods of engineering iPSC cells. The portfolio includes composition of matter claims covering our CNTY-101, CNTY-102 and CNTY-107 products, as well as other iPSC-derived engineered CAR cells comprising certain transgene insertions and deletions, including our proprietary Allo-Evasion™ technology. One of our provisional patent applications includes claims directed to a universal CAR cell platform. We have also filed patent applications relating to our T-cell platform related to compositions and methods for generating alpha-beta and gamma delta T cells from iPSCs. We have also filed patent applications related to a novel safety switch. Any U.S. patents that may issue from such pending provisional patent applications would expire in from 2040-2042, without giving effect to any patent term adjustment or extension.

Intellectual property relating to engineered T cells

We have exclusively sublicensed from iCELL two families of patents owned by the University of Tokyo relating to immune function reconstruction method using multipotent stem cells and method for producing antigen-specific T cells. The portfolio includes two issued U.S. patents claiming methods for the production of T cells having antigen specificity from iPSC cells derived from human T cells where the T cells differentiated from the iPSC cells retain the antigen specificity of the human T cell from which it was derived. These issued patents will expire in 2031, without giving effect to any patent term adjustment or extension.

Competition

The biotechnology and pharmaceutical industries have made substantial investments in recent years into the rapid development of novel immunotherapies for the treatment of a range of pathologies, including infectious diseases and cancers, making this a highly competitive market.

We face substantial competition from multiple sources, including large and specialty pharmaceutical, biopharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, technologies, and data emerge within the field of immunotherapy and, furthermore, within the treatment of infectious diseases and cancers. In addition to the current standard of care treatments for patients with infectious diseases or cancers, numerous commercial and academic preclinical studies and clinical trials are being undertaken by a large number of parties to assess novel technologies and product candidates in the field of immunotherapy. Results from these studies and trials have fueled increasing levels of interest in the field of immunotherapy.

Large pharmaceutical companies that have commercialized or are developing immunotherapies to treat cancer include AstraZeneca, Bristol-Myers Squibb, Gilead Sciences, Merck, Novartis, Pfizer, and Roche/Genentech.

Companies that compete with us directly on the level of the development of product candidates targeting B-cell lymphomas include Gilead Sciences, Novartis and Bristol-Myers Squibb, among others. Companies developing Nectin-4 targeted agents include Seagen, Astellas and Bicycle Therapeutics.

On the technology level, other emerging biopharmaceutical companies which can potentially develop competing cell therapy candidates to treat cancer include Editas Medicine, Inc., Fate Therapeutics, Allogene Therapeutics, CRIPSR Therapeutics, Caribou Biosciences, Cytovia Therapeutics, Shoreline Biosciences, Sana Biotechnology and Nkarta Therapeutics.

Many of our competitors, either alone or in combination with their respective strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, the regulatory approval process, and marketing than we do. Mergers and acquisition activity in the pharmaceutical, biopharmaceutical and biotechnology sector is likely to result in greater resource concentration among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through sizeable collaborative arrangements with established companies. These competitors also compete with us in recruiting and retain qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if one or more of our competitors develop and commercialize products that are safer, more effective, better tolerated, or of greater convenience or economic benefit than our proposed product offering. Our competitors also may be in a position to obtain FDA or other regulatory approval for their products more rapidly, resulting in a stronger or dominant market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be product safety, efficacy, convenience and treatment cost.

Government regulation

In the United States, biologic products are licensed by FDA for marketing under the Public Health Service Act, referred to as the PHS Act, and regulated under the Federal Food, Drug, and Cosmetic Act, or the FDCA. Both the FDCA and the PHS Act and their corresponding regulations govern, among other things, the testing, manufacturing, safety, purity, potency, efficacy, labeling, packaging, storage, record keeping, distribution, marketing, sales, import, export, reporting, advertising and other promotional practices involving biologic products. FDA clearance must be obtained before clinical testing of biologic products. FDA licensure also must be obtained before marketing of biologic products. 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.

United States development process

The process required by the FDA before a biologic 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 cGLP, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- preparation of clinical trial material in accordance with cGMP;

- submission to the FDA of an application for an IND, which must become effective before human clinical trials may begin;
- approval by an institutional review board, or IRB, reviewing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to Current Good Clinical Practices, or cGCP, and any additional requirements for the protection of human research subjects and their health information, to establish the safety, purity, potency, and efficacy, of the proposed biologic product for its intended use;
- submission to the FDA of a Biologics License Application, or BLA, for marketing approval that includes substantive evidence of safety, purity, potency, and efficacy from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection prior to BLA approval of the manufacturing facility or facilities where the biologic product is produced to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality and purity;
- potential FDA audit of the nonclinical and clinical study sites that generated the data in support of the BLA;
- potential FDA Advisory Committee meeting to elicit expert input on critical issues and including a vote by external committee members;
- FDA review and approval, or licensure, of the BLA, and payment of associated user fees, when applicable; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategies, or REMS, and the potential requirement to conduct post-approval studies.

Before testing any biologic product candidate in humans, the product candidate enters the preclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, pharmacology, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the nonclinical tests must comply with federal regulations and requirements including GLPs.

The clinical study sponsor must submit the results of the nonclinical 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 nonclinical testing typically continues after the IND is submitted. An IND is an exemption from the FDCA that allows an unapproved product to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational product to humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA requests certain changes to a protocol before the trial can begin, or the FDA places the clinical 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 biologic 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.

Clinical trials may involve the administration of the biologic product candidate to healthy volunteers or subjects under the supervision of qualified investigators, generally physicians not employed by or under the

study sponsor's control. Clinical trials involving some products for certain diseases, including some rare diseases, may begin with testing in patients with the disease. 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 cGCP requirements, including the requirement that all research subjects or his or her legal representative 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 study 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. Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee.

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

- **Phase 1.** The biologic product is initially introduced into healthy human subjects and tested for safety. In the case of some products for rare and severe diseases, the initial human testing is often conducted in patients.
- **Phase 2.** The biologic 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/benefit ratio of the product and provide an adequate basis for product labeling. In biologics for rare diseases where patient populations are small and there is an urgent need for treatment, Phase 3 trials might not be required if an adequate risk/benefit can be demonstrated from the Phase 2 trial.

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 subjects, 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 a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biologic has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biologic 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 biologics, the PHS Act 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.

There are also various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with the research. In each of these areas, the FDA and other regulatory authorities have broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals.

Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on its clinicaltrials.gov website. Sponsors or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must also have a publicly available policy on evaluating and responding to requests for expanded access requests.

United States 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 product. The BLA must include results of product development, laboratory and animal studies, human studies, 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 may be accompanied by a significant user fee. Under federal law, the submission of most applications is subject to an application user fee. The sponsor of an approved application is also subject to an annual program fee. 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 product candidates designated as orphan drugs, unless the product candidate 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 is also subject to review before the FDA accepts it for filing. The application also needs to be published and submitted in an electronic format that can be processed through the FDA's electronic systems. If the electronic submission is not compatible with FDA's systems, the BLA can be refused 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 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 products or 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 REMS is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA may inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical trial sites to assure that the clinical trials were conducted in compliance with IND study requirements and cGCP requirements. To assure cGMP and cGCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control. 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 the sponsor interprets 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 usually 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 product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product 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 products that have been commercialized. As a condition for approval, the FDA may also require additional nonclinical testing as a Phase 4 commitment.

One of the performance goals agreed to by the FDA under the PDUFA is to review standard BLAs in ten months from filing and priority BLAs in six months from filing, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

United States post-approval requirements

Maintaining substantial compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP. We will rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation.

Following approval, the manufacturing facilities are subject to biennial inspections by the FDA's and such inspections may result in an issuance of FDA Form 483 deficiency observations, untitled letter, or a warning letter, which can lead to plant shutdown and other more serious penalties and fines. Prior to the institution of

any manufacturing changes, a determination needs to be made whether FDA approval is required in advance. If not done in accordance with FDA expectations, the FDA may restrict supply and may take further action. Annual product reports are required to be submitted annually. Other post-approval requirements applicable to biological products, include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse events, reporting updated safety and efficacy information, and complying with electronic record and signature requirements.

After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA may conduct laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. Systems need to be put in place to record and evaluate adverse events reported by health care providers and patients and to assess product complaints. An increase in severity or new adverse events can result in labeling changes or product recall. Defects in manufacturing of commercial products can result in product recalls.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or inpatient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. 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 or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval or license revocation, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological 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. Accordingly, manufacturers must continue to expend time, money, and effort in the areas 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 withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation, or ODD, to a biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a biological product available in the United States for this type of disease or condition will be recovered from sales of the product. ODD must be requested before submitting a BLA. After the FDA grants ODD, the identity of the therapeutic agent and its

potential orphan use are disclosed publicly by the FDA. ODD does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has ODD receives the first FDA approval for the disease or condition 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 to market the same biological product for the same indication for seven years, except in limited circumstances, such as not being able to supply the product for patients or showing clinical superiority to the product with orphan exclusivity.

Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity.

Expedited review and approval programs

The FDA has various programs, including fast track designation, priority review, accelerated approval, and breakthrough therapy designation, that are intended to expedite or simplify the process for the development and FDA review of biological products that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new biological products to patients earlier than under standard FDA review procedures. To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a biological product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a fast track BLA before the application is complete, a process known as rolling review.

The FDA may give priority review designation to biological products that treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Most products that are eligible for fast track designation may also be considered appropriate to receive a priority review. In addition, biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the biological 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 a sponsor of a biological product receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. Sponsors are also required to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. In addition, the FDA generally requires,

unless otherwise informed by the agency, pre-approval of promotional materials for a product approved under the accelerated approval pathway, which could adversely impact the timing of the commercial launch of the product.

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

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

Biologics Price Competition and Innovation Act

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, which was enacted as part of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or PPACA, created an abbreviated approval pathway for biological products that are demonstrated to be “biosimilar” or “interchangeable” with an FDA-licensed reference biological product via an approved BLA. Biosimilarity to an approved reference product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity is demonstrated in steps beginning with rigorous analytical studies or “fingerprinting,” in vitro studies, in vivo animal studies, and generally at least one clinical study, absent a waiver from the Secretary of Health and Human Services. The biosimilarity exercise tests the hypothesis that the investigational product and the reference product are the same. If at any point in the stepwise biosimilarity process a significant difference is observed, then the products are not biosimilar, and the development of a stand-alone BLA is necessary. In order to meet the higher hurdle of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product, and for a product that is administered more than once, that the risk of switching between the reference product and biosimilar product is not greater than the risk of maintaining the patient on the reference product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being evaluated by the FDA. Under the BPCIA, a reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product.

Regulation outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing clinical studies, commercial sales, and distribution of our products. Most countries outside of the United States require that CTAs be submitted to and approved by the local regulatory authority for each clinical study. In the European Union, for example, an application must be submitted to the national competent authority and an independent ethics committee in each country in which we intend to conduct clinical trials, much like the FDA and IRB, respectively. Under the new Clinical Trials Regulation (EU) No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC on January 31, 2022, a single application is now made through the Clinical Trials Information System, or CTIS, for clinical trial authorization in up to 30 EU/EEA countries at the same time and with a single set of documentation.

The assessment of applications for clinical trials is divided into two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all European Union Member States in which an application for authorization of a clinical trial has been submitted (Concerned Member States) of a draft report prepared by a Reference Member State. Part II is assessed separately by each Concerned Member State. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the Concerned Member State, however overall related timelines are defined by the Clinical Trials Regulation. The new Clinical Trials Regulation also provides for simplified reporting procedures for clinical trial sponsors.

In addition, whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of countries outside the United States before we can market the product in those countries. The approval process and requirements vary from country to country, so the number and type of nonclinical, clinical, and manufacturing studies needed may differ, and the time may be longer or shorter than that required for FDA approval.

To obtain regulatory approval of our product candidates under the European Union regulatory system, we are required to submit a marketing authorization application, or MAA, to be assessed in the centralized procedure. The centralized procedure allows applicants to obtain a marketing authorization, or MA, that is valid throughout the European Union, and the additional Member States of the European Economic Area (Iceland, Liechtenstein and Norway), or EEA. It is compulsory for medicinal products manufactured using biotechnological processes, for orphan medicinal products, for advanced therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and for human products containing a new active substance which are not authorized in the European Union and which are intended for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, auto-immune and other immune dysfunctions, viral diseases or diabetes. The centralized procedure is optional for any other products containing new active substances not authorized in the European Union or for products that constitute a significant therapeutic, scientific or technical innovation or for which a centralized authorization is in the interests of patients at European Union level. When a company wishes to place on the market a medicinal product that is eligible for the centralized procedure, it sends an application directly to the European Medicines Agency, or EMA, to be assessed by the Committee for Medicinal Products for Human Use, or CHMP. The CHMP is responsible for conducting the assessment of whether a medicine meets the required quality, safety and efficacy requirements, and whether the product has a positive risk/benefit profile. The procedure results in a European Commission decision, which is valid in all European Union Member States. The centralized procedure is as follows: full copies of the MA are sent to a rapporteur and a co-rapporteur designated by the competent EMA scientific committee. They coordinate the EMA's scientific assessment of the medicinal product and prepare draft reports. Once the draft reports are prepared (other experts might be called upon for this purpose), they are sent to the CHMP, whose comments or objections are communicated to the applicant. The rapporteur is therefore the privileged interlocutor of the applicant and continues to play this role, even after the MA has been granted.

The rapporteur and co-rapporteur then assess the applicant's replies, submit them for discussion to the CHMP and, taking into account the conclusions of this debate, prepare a final assessment report. Once the evaluation is completed, the CHMP gives a favorable or unfavorable opinion as to whether to grant the authorization. When the opinion is favorable, it shall include the draft summary of product characteristics, or SmPC, the package leaflet and the labeling. The time limit for the evaluation procedure is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). The EMA then has fifteen days to forward its opinion to the European Commission, which will make a binding decision on the grant of an MA within 67 days of the receipt of the CHMP opinion.

There are two other procedures in the European Union for the grant of an MA in multiple European Union Member States. The decentralized procedure provides for approval by one or more other, or Concerned, Member States of an assessment of an application performed by one Member State, known as the Reference

Member State. Under this procedure, an applicant submits an application, or dossier, and related materials including a draft SmPC, and draft labeling and package leaflet, to the Reference Member State and Concerned Member States. The Reference Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the Reference Member State's assessment report, each Concerned Member State must decide whether to approve the assessment report and related materials. If a Member State cannot approve the assessment report and related materials on the grounds of potential serious risk to the public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all Member States.

The criteria for designating an "orphan medicinal product" in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 1411/2000, a medicinal product may be designated as an orphan medicinal product if it is intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition that affects no more than five in 10,000 persons in the European Union. In addition, orphan designation can be granted if the product is intended for a life threatening, seriously debilitating, or serious and chronic condition in the European Union and where, without incentives, it is unlikely that sales of the product in the European Union would be sufficient to justify the necessary investment in its development. Orphan drug designation is only available if there is no other satisfactory method approved in the European Union of diagnosing, preventing, or treating the applicable orphan condition, or if such a method exists, the proposed orphan drug will be of significant benefit to patients affected by such condition, as defined in Regulation (EC) 847/2000.

Orphan designation provides opportunities for fee reductions, protocol assistance and access to the centralized procedure before and during the first year after a marketing authorization. Fee reductions are not limited to the first year after a marketing authorization for small and medium enterprises. In addition, if a product that has an orphan designation subsequently receives a centralized MA for the indication for which it has such designation, the product is entitled to orphan market exclusivity, which means the EMA may not approve any other application to market a similar medicinal product for the same indication for a period of ten years. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The exclusivity period may be reduced to six years if the designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Competitors may receive marketing approval of different drugs or biologics for the indications for which the orphan product has exclusivity. Additionally, an MA may be granted to a similar medicinal product for the same indication at any time if:

- the second applicant can establish that its product, although similar to the authorized orphan product, is safer, more effective or otherwise clinically superior;
- the MA holder of the authorized product consents to a second orphan medicinal product application; or
- the MA holder of the authorized product cannot supply enough orphan medicinal product.

A pediatric investigation plan, or PIP, in the European Union is aimed at ensuring that the necessary data are obtained to support the authorization of a medicine for children, through studies in children. All applications for MAs for new medicines have to include the results of studies as described in an agreed PIP, unless the medicine is exempt because of a deferral or waiver. This requirement also applies when a marketing-authorization holder wants to add a new indication, pharmaceutical form, or route of administration for a medicine that is already authorized and covered by intellectual property rights. Several rewards and incentives for the development of pediatric medicines for children are available in the European Union. Medicines authorized across the European Union with the results of studies from a PIP included in the product information are eligible for an extension of their supplementary protection certificate, or SPC, by six months (provided an application for such extension is made at the same time as filing the SPC application for the product, or at any point up to 2 years before the SPC expires). This is the case even when the studies'

results are negative. For orphan medicinal products, the incentive is an additional two years of market exclusivity.

Scientific advice and protocol assistance at the EMA are free of charge for questions relating to the development of pediatric medicines. Medicines developed specifically for children that are already authorized but are not protected by a patent or supplementary protection certificate are eligible for a pediatric-use MA, or PUMA. If a PUMA is granted, the product will benefit from ten years of market protection as an incentive.

In March 2016, the EMA launched an initiative, The PRiority Medicines, or PRIME, scheme, to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIME scheme is intended to encourage development of products in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted.

Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

The aforementioned European Union rules are generally applicable in the EEA.

The United Kingdom left the European Union on January 31, 2020, referred to as Brexit, and the United Kingdom and the European Union have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of United Kingdom and European Union pharmaceutical regulations. At present, Great Britain has implemented European Union legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the European Union regulatory framework continues to apply in Northern Ireland). Except in respect of the new EU Clinical Trials Regulation, the regulatory regime in Great Britain therefore largely aligns with current European Union medicines regulations, however it is possible that these regimes will diverge more significantly in future now that Great Britain's regulatory system is independent from the European Union and the TCA does not provide for mutual recognition of United Kingdom and European Union pharmaceutical legislation. However, notwithstanding that there is no wholesale recognition of European Union pharmaceutical legislation under the TCA, under the new framework mentioned below which will be put in place by the MHRA from January 1, 2024, the MHRA has stated that it will take into account decisions on the approval of MAs from the EMA (and certain other regulators) when considering an application for a Great Britain MA.

The Medicines and Healthcare products Regulatory Agency, or MHRA, the United Kingdom's medicines regulator, has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, an accelerated assessment procedure and new routes of evaluation for novel products and biotechnological products. All existing European Union MAs for centrally authorized products were automatically converted (grandfathered) into United Kingdom MAs free-of-charge on January 1, 2021. For a period of three years from January 1, 2021, the MHRA may rely on a decision taken by the European Commission on the approval of a new MA in the centralized procedure, in order to more quickly grant a new Great Britain MA. A separate application will, however, still be required. On January 24, 2023, the MHRA announced that a new international recognition framework will be put in place from January 1, 2024, which will have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new Great Britain MA.

There is now no pre-MA orphan designation in Great Britain. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MAA. The criteria are essentially the same, but have been tailored for the Great Britain market, i.e., the prevalence of the condition in Great Britain (rather than the European Union) must not be more than five in 10,000. Should an orphan designation be granted, the period or market exclusivity will be set from the date of first approval of the product in Great Britain or the European Union, wherever is earliest.

Healthcare laws and regulations

Sales of our product candidate, if approved, or any other future product candidate will be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we might conduct our business. The healthcare laws and regulations that may affect our ability to operate include the following:

- The federal Anti-Kickback Statute makes it illegal for any person or entity to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is in exchange for or to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term “remuneration” has been broadly interpreted to include anything of value;
- Federal false claims and false statement laws, including the federal civil False Claims Act, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs and biologics, that are false or fraudulent;
- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors or making any false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their implementing regulations, impose obligations on certain types of individuals and entities regarding the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information;
- The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, certified nurse-midwives, and physician assistants, as well as ownership and investment interests held by physicians and their immediate family members; and
- The Foreign Corrupt Practices Act, or FCPA prohibits United States businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business.

Many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, we may be subject to state laws that require pharmaceutical

companies to comply with the federal government's and/or pharmaceutical industry's voluntary compliance guidelines, state laws that require drug and biologics manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, as well as state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

Healthcare Reform

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government- paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs and biologics. In recent years, the United States Congress, or Congress, has considered reductions in Medicare reimbursement levels for drugs and biologics administered by physicians. CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some drugs and biologics. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Among other things, the Affordable Care Act expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum Medicaid rebate for both branded and generic drugs and biologics, expanded the 340B program, and revised the definition of average manufacturer price, or AMP, which could increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also extended Medicaid drug rebates, previously due only on fee-for- service Medicaid utilization, to include the utilization of Medicaid managed care organizations as well and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. These regulations became effective on April 1, 2016. The Tax Cuts and Jobs Act, enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, as amended, or the Code, commonly referred to as the individual mandate.

Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than \$1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2% per fiscal year, which went into effect in April 2013. Subsequent litigation extended the 2% reduction, on average, to 2030. However, pursuant to the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, the 2% Medicare sequester reductions have been suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the suspension, a 1% payment reduction began April 1, 2022, and remained through

June 30, 2022. The 2% payment reduction resumed on July 1, 2022. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, 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.

Further legislative and regulatory changes under the Affordable Care Act remain possible. It is unknown what form any such changes or any law would take, and how or whether it may affect our business in the future. We expect that changes or additions to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

The Affordable Care Act has been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. An appeal was taken to the U.S. Supreme Court. The Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions.

The Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs and biologics to pay a branded prescription drug fee to the federal government. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Furthermore, the law requires manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the “donut hole.” The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole,” by increasing from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D.

The Affordable Care Act also expanded the Public Health Service’s 340B drug pricing program. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B “ceiling price” for the manufacturer’s covered outpatient drugs. The Affordable Care Act expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Affordable Care Act. Because the 340B ceiling price is determined based on the average manufacturer price, or AMP, and Medicaid drug rebate data, revisions to the Medicaid rebate formula and AMP definition could cause the required 340B discounts to increase. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives as well. For example, CMS may develop new payment and delivery models, such as bundled payment models. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for pharmaceutical products.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Human capital resources

As of March 2, 2023, we had 163 full-time employees and 21 part-time employees. Of our 184 full and part-time employees, 151 are engaged in research and development activities. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity 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. We regularly evaluate our compensation programs with an independent compensation consultant and utilize industry benchmarking in an effort to ensure competitiveness compared to similar biotechnology and biopharmaceutical companies with which we compete for talent, as well as fair and equitable treatment across our workforce with respect to gender, race, and other personal characteristics.

We are an equal opportunity employer and we maintain policies that prohibit unlawful discrimination based on race, color, religion, gender, sexual orientation, gender identity/expression, national origin/ancestry, age, disability, marital and veteran status. Our employees are not part of any collective bargaining agreements and we believe that we have good relations with our employees.

Facilities

Our principal executive offices are located in Philadelphia, Pennsylvania, pursuant to a short-term lease. We operate in three laboratory spaces in Philadelphia pursuant to leases that expire in December 2030, October 2031 and February 2034. Additionally, we lease office and laboratory space in Seattle, Washington pursuant to leases expiring in September 2030, respectively and laboratory and office space in Hamilton, Ontario, pursuant to a lease that expires in October 2025. We have finished construction and the operational fit out of a 53,000 square foot cell therapy manufacturing facility on a tract of land in Branchburg, New Jersey pursuant to a lease expiring in February 2037. We believe that our current facilities are adequate to meet our ongoing needs, and that, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

Legal proceedings

We are not currently a party to any material legal proceedings. From time to time, we may become involved in other litigation or legal proceedings relating to claims arising from the ordinary course of business.

Available Information

Our website address is www.centurytx.com. Our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, any amendments to those reports, proxy and registration statements filed or furnished with the Securities and Exchange Commission, or SEC, are available free of charge through our website. We make these materials available through our website as soon as reasonably practicable after we electronically file such materials with, or furnish such materials to, the SEC. The reports filed with the SEC by our executive officers and directors pursuant to Section 16 under the Exchange Act are also made available, free of charge on our website, as soon as reasonably practicable after copies of those filings are provided to us by those persons. These materials can be accessed through the "Investors-Financial Information" section of our website. The information contained in, or that can be accessed through, our website is not part of this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS

Risk Factor Summary

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under “Cautionary Note Regarding Forward-Looking Statements” and “Risk Factors” in this Annual Report on Form 10-K. The below summary is qualified in its entirety by those more complete discussions of such risks and uncertainties.

- We have a limited operating history, have incurred significant losses since our inception, and anticipate that we will continue to incur significant losses in the foreseeable future;
- We have never generated revenue from product sales and may never achieve or maintain profitability;
- We are early in our development efforts and our business is dependent on our ability to advance our current and future product candidates through preclinical studies and clinical trials, obtain marketing approval and ultimately commercialize our current and future product candidates;
- We are highly dependent on the success of our lead product candidate, CNTY-101, which is currently undergoing a phase I clinical trial, and our other product candidates;
- We are highly dependent on our strategic relationships and collaborations and any termination or loss of significant rights under such arrangements with our strategic partners could seriously harm our business;
- The COVID-19 pandemic, or a similar global health crisis may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates;
- Utilizing CAR-iNK and CAR-iT cells represents a novel approach to immuno-oncology treatment of cancer, and we must overcome significant challenges in order to develop, commercialize, and manufacture our product candidates;
- Gene-editing is a rapidly developing technology, and our success is dependent upon our ability to effectively utilize this technology in our product candidates and implement future technological advancements in gene-editing;
- Preclinical and clinical development involve a lengthy and expensive process with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates;
- As an organization, we have limited experience designing or implementing clinical trials. Failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect the ability to initiate the trial, enroll patients, complete the trial, or obtain regulatory approval on the basis of the trial results, as well as lead to increased or unexpected costs;
- The manufacture and distribution of our iPSC-derived cell product candidates is complex and subject to a multitude of risks;
- We currently utilize our own manufacturing facility as well third parties for the manufacture of our product candidates for development. Operational issues with our own facility or with third party facilities could delay our development plans and thereby limit our ability to generate revenue;

- We could become dependent on Bristol-Myers Squibb Company, or Bristol-Myers Squibb, for development and commercialization activities with respect to certain of our product candidates pursuant to our collaboration with Bristol-Myers Squibb and cannot control whether Bristol-Myers Squibb will devote sufficient attention or resources to this collaboration or proceed in an expeditious manner;
- If we are unable to successfully commercialize CNTY-101 or any of our other product candidates for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed;
- We face significant competition, and if our competitors develop product candidates more rapidly than we do or their product candidates are more effective, our ability to develop and successfully commercialize products may be adversely affected;
- We may face difficulties in obtaining, protecting, maintaining, and enforcing our intellectual property rights, including intellectual property rights that are licensed to us;
- We do not currently own any issued patents relating to our product candidates;
- Unstable market and economic conditions, including inflation and political unrest, may have serious adverse consequences on our business, financial condition, and stock price;
- The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses; and
- Our executive officers, directors, principal stockholders, and affiliates continue to exercise significant control over our company, which limits the ability of our other stockholders to influence corporate matters and could delay or prevent a change in corporate control.

Risk Factors

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. The risks described below are not the only ones facing us. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could significantly harm our business, financial condition, results of operations and growth prospects.

Risks related to our financial position and capital requirements

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are an early stage biopharmaceutical company with a limited operating history. Our operations to date have been limited raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies, in-licensing intellectual property, establishing manufacturing processes and initiating a phase I clinical trial. All but one of our product candidates are still in the discovery and preclinical testing phase, and in February 2023, we began dosing patients in our first phase I clinical trial, ELiPSE-1, evaluating CNTY-101. We have not yet demonstrated our ability to successfully complete a clinical trial, or submit a biologics license application, or BLA, for a product candidate, obtain regulatory approval for any product candidate, manufacture a product at a commercial-scale or arrange for a third party to do so on our behalf, or conduct sales, marketing, and distribution activities necessary for successful product commercialization. Consequently, any assumptions you make about our future success or viability may not be as informed as they could be if we had a longer operating history.

We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future.

We have incurred significant operating losses since our inception. If our product candidates are not successfully developed and approved, we may never generate any revenue. Our net losses for the years ended December 31, 2022 and 2021 were \$130.9 million and \$95.8 million, respectively. As of December 31, 2022, we had an accumulated deficit of \$519.1 million.

Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs, the preparation and inception of our phase I clinical trial, ELIPSE-1, the acquisition of IPR&D and from general and administrative costs associated with our operations. All of our product candidates will require the expenditure of substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin realizing product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, seek regulatory approval for, and potentially commercialize any of our product candidates and seek to identify, assess, acquire, in-license, or develop additional product candidates. Our prior losses, combined with expected future losses, have had and will continue to have a negative effect on our stockholders' deficit and working capital.

We expect that it will be several years, if ever, before we have a commercialized product. We anticipate that our expenses will increase substantially if, and as, we:

- continue to advance our induced pluripotent stem cells, or iPSC-derived allogeneic, cell therapy platforms;
- continue the clinical development of CNTY-101 and the preclinical and clinical development of our other product candidates;
- seek to discover and develop additional product candidates;
- establish and validate our own clinical-scale current good manufacturing practices, or cGMP, facilities;
- seek regulatory approvals for any of our other product candidates that successfully complete clinical trials;
- maintain, expand, protect, and enforce our intellectual property portfolio;
- acquire or in-license other product candidates and technologies;
- incur additional costs associated with operating as a public company, such as operational, financial, and management information systems and personnel, including personnel to support our drug development, any future commercialization efforts; and
- increase our employee headcount and related expenses to support these activities.

We may never succeed in any or all of these activities and, even if we do, we may never generate revenue.

We have never generated revenue from product sales and may never achieve or maintain profitability.

We have one product candidate in clinical development and no product candidates approved for commercial sale and have not generated any revenue. To become and remain profitable, we must develop and eventually commercialize product candidates with significant market potential, which will require us to be successful in a range of challenging activities. These activities can include completing preclinical studies and initiating and completing clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing, and selling those products that are approved and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate sufficient revenues to achieve profitability. Because of the numerous risks and uncertainties associated with biologics product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations.

We will require additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive, and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct preclinical activities and clinical trials of, and seek regulatory and marketing approval for, our product candidates. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. We have financed our operations primarily through private placements of our securities and our initial public offering of common stock, or IPO, which closed in June 2021. Our research and development expenses increased from \$75.7 million for the year ended December 31, 2021 to \$97.2 million for the year ended December 31, 2022. As of December 31, 2022, we had cash, and cash equivalents of \$84.3 million and investments of \$283.1 million. Based on our research and development plans, we believe our existing cash, cash equivalents and investments will be sufficient to fund our operating expenses and capital expenditures requirements into 2026.

Attempting to secure additional financing will divert our management from our day-to-day activities, which may impair or delay our ability to develop our product candidates. In addition, demands on our cash resources may change as a result of many factors currently unknown to us including, but not limited to, any unforeseen costs we may incur as a result of preclinical study or clinical trial delays, and we may need to seek additional funds sooner than planned. If we are unable to obtain funding on a timely basis or at all, we may be required to significantly curtail or stop one or more of our research or development programs.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until and unless we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings and debt financings, and potentially through additional license and development agreements or strategic partnerships or collaborations with third parties. Financing may not be available in sufficient amounts or on reasonable terms. In addition, market volatility resulting from inflation, pandemics, political unrest and hostilities, or other factors could adversely impact our ability to access capital as and when needed. We have no commitments for any additional financing, and will likely be required to raise such financing through the sale of additional securities. If we sell equity or equity-linked securities, our current stockholders may be diluted, and the terms may include liquidation or other preferences that are senior to or otherwise adversely affect the rights of our stockholders. In July 2022, we entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to \$150 million from time to time through Cowen acting as our sales agent, or the 2022 ATM Facility. There have been no sales of shares of our common stock under the 2022 ATM Facility through the date of the filing of this Annual Report on Form 10-K. Moreover, if we issue debt, we may need to dedicate a substantial portion of our operating cash flow to paying principal and interest on such debt and we may need to comply with operating restrictions, such as limitations on incurring additional debt, which could impair our ability to acquire, sell, or license intellectual property rights and impede our ability to conduct our business. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline.

If we raise funds through additional licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses under our intellectual property on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability.

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

To the extent that we continue to generate taxable losses, subject to certain limitations, unused losses will carryforward to offset future taxable income, if any, until such unused losses expire. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an ownership change (generally defined as a greater than 50 percentage points change (by value) in its equity ownership over a rolling three-year period), the corporation's ability to use its pre-change net operating losses and other pre-change tax attributes to offset its post-change income may be limited. We were formed in 2018 as Century Therapeutics, Inc., or Prior Century. In 2019, in connection with our investment from Bayer Prior Century contributed substantially all of its operating assets and cash to a newly formed entity, Century Therapeutics, LLC. Our business was operated through Century Therapeutics, LLC, until February 2021, at which time we converted into a Delaware C corporation. Upon completion of this conversion, Prior Century, whose only significant asset was its equity investment in Century Therapeutics, LLC, merged with the C corporation, and in connection therewith the C corporation changed its name to "Century Therapeutics, Inc." We believe that Prior Century or we may have experienced an ownership change in the past, which may affect our ability to utilize our net operating loss carryforwards. In addition, we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. Similar limitations will apply to our ability to carry forward any unused tax credits to offset future taxable income.

Changes in tax law may adversely affect us or our investors.

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 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 common stock. For example, under Section 174 of the Code, in taxable years beginning after December

31, 2021, expenses that are incurred for research and development in the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. In recent years, many such changes have been made, and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

Our Option Agreement with Bayer HealthCare LLC may require us to sell certain of our product candidates, which may limit the value we could generate from our product candidates.

We are party to an option agreement, or the Option Agreement, with Bayer HealthCare LLC, or Bayer, pursuant to which Bayer was granted certain bidding rights relating to the potential transfer of rights with respect to certain product candidates being researched and developed by us which are comprised of allogeneic iPSC-derived natural killer cells, macrophages or dendritic cells, which we refer to as the Research Products. Under the Option Agreement, Bayer was granted a right of first refusal, or ROFR, to submit bids for the transfer or license of rights to research, develop and/or commercialize certain Research Products, which we refer to as the Research Product Rights. While CNTY-101 is no longer included in the Bayer option rights, any other wholly owned product candidate comprised of iNK cells that we develop in the future are subject to the terms of the Option Agreement. Bayer may exercise its ROFR for up to four of the first ten Research Products for which an IND is submitted, subject to certain limitations.

If Bayer exercises its ROFR for one of our Research Products, we may be required to transfer such Research Product (by sale, license, or other structure to be negotiated) to Bayer for a market value as determined by our board of directors, and such determination of market value may ultimately prove to be lower than the actual realizable value of applicable Research Product. There can be no guarantee that we will utilize the proceeds received in connection with the exercise of Bayer's ROFR in a manner which will provide us with greater value than if we had retained the Research Product or sold such Research Product to another party. Any failure to realize or utilize the full value of our Research Products due to the Option Agreement could have a material adverse effect on our business, financial condition, and results of operation.

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 several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. We cannot assure you that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy and ability to raise capital may be adversely affected by any such economic downturn, volatile business environment, or continued unpredictable and unstable market conditions, including as a result of liquidity constraints, failures and instability in U.S. and international financial banking systems. If the current equity and credit markets deteriorate further, or fail to improve, 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 growth strategy, financial performance, and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers, and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, including in connection with the COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Further, the impacts of political unrest, including as a result geopolitical tension, such as a deterioration in the relationship between the United States and China or the conflict between Russia and Ukraine, including any additional sanctions, export controls or other restrictive actions that may be imposed by the United States and/or other countries against governmental or other entities could lead to disruption, instability and volatility in the global markets, which may have an adverse impact on our business or ability to access the capital markets. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects, or developments relating to pandemics, political, regulatory, and other market conditions, may negatively affect the market price of shares of our common stock, regardless of our actual operating performance.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and financial condition and results of operations.

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Most recently, on March 10, 2023, Silicon Valley Bank (“SVB”) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (“FDIC”) as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. Even though we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our business, financial condition or results of operations.

Risks related to our business and industry

We are very early in our development efforts. Our business is dependent on our ability to advance our current and future product candidates through preclinical studies and clinical trials, obtain marketing approval, and ultimately commercialize them.

We are very early in our development efforts and we have only recently initiated our first Phase 1 clinical trial for CNTY-101. Additionally, we are actively engaged in a number of earlier stage discovery programs that may never advance to clinical-stage development. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from product sales and we may never be able to develop or commercialize a marketable product.

Each of our product candidates will require additional preclinical and/or clinical development, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, capacity and expertise, building a commercial organization, or successfully outsourcing commercialization, substantial investment, and significant marketing efforts before we generate any revenue from product sales. Our product candidates must be authorized for marketing by the U.S. Food and Drug Administration, or the FDA, or certain other foreign regulatory agencies before we may commercialize our product candidates.

The clinical and commercial success of our product candidates will depend on several factors, including the following:

- timely and successful completion of preclinical studies, including toxicology studies, biodistribution studies, and minimally efficacious dose studies in animals, where applicable, and in accordance with Good Laboratory Practices, or GLPs;
- effective INDs or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for our product candidates;
- successful enrollment and completion of clinical trials, including under the FDA's current Good Clinical Practices, or cGCPs, and GLPs;
- positive results from our ongoing, planned and future clinical programs that support a finding of safety and effectiveness and an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt of marketing approvals from applicable regulatory authorities;
- establishment of arrangements with CMOs for clinical supply and, where applicable, commercial manufacturing capabilities;
- establishment and maintenance of patent and trade secret protection, and/or regulatory exclusivity for our product candidates

- commercial launch of our product candidates, if approved, whether alone or in collaboration with others;
- acceptance of the benefits and use of our product candidates, including method of administration, if and when approved, by patients, the medical community, and third-party payors;
- effective competition with other therapies;
- establishment and maintenance of healthcare coverage and adequate reimbursement and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement;
- establishment of a physician training system and network for administration of our product candidates;
- enforcement and defense of intellectual property rights and claims; and
- maintenance of a continued acceptable safety, tolerability, and efficacy profile of our product candidates following approval.

If we do not succeed in one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, if approved, which would materially harm our business. If we are unable to advance our product candidates to clinical development, obtain regulatory approval, and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

Our business is highly dependent on the success of our lead product candidate, CNTY-101 and our other product candidates.

While we have successfully initiated the clinical development of CNTY-101, we cannot guarantee that an IND application will be cleared to proceed after submission to the FDA for any of our other product candidates or that CNTY-101 or our other product candidates will be approved for commercialization, on a timely basis or at all. Although certain of our employees have prior experience with clinical trials and regulatory approvals, we have not previously completed any clinical trials or submitted a BLA to the FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that CNTY-101 or our other product candidates will be successful in clinical trials or receive regulatory approval. The FDA and other comparable global regulatory authorities can delay, limit, or deny approval of a product candidate for many reasons. Any delay in obtaining, or inability to obtain, applicable regulatory approval will delay or harm our ability to successfully develop and commercialize CNTY-101 or our other product candidates and materially adversely affect our business, financial condition, results of operations, and growth prospects.

Furthermore, if our clinical trials of CNTY-101 or our other product candidates encounter safety, efficacy, or manufacturing problems, development delays, regulatory issues, or other problems, our development plans for such product candidates in our pipeline could be significantly impaired, which could materially adversely affect our business, financial condition, results of operations, and growth prospects.

We may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop or combination therapy, we may be unable to obtain approval of or market our product candidates.

Our business depends upon the success of our iPSC-derived allogeneic cell therapy platforms.

Our success depends on our ability to utilize our iPSC-derived allogeneic cell therapy platforms to generate chimeric antigen receptors, or CAR-iNK and CAR-iT cell product candidates, to obtain regulatory approval for product candidates derived from it, and to then commercialize our product candidates addressing one or more indications. Though iPSC-derived cell therapy product candidates have been evaluated by others in clinical trials, our product candidates have never been evaluated in human clinical trials, and we may experience unexpected or adverse results in the future. We are exposed to a number of unforeseen risks and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates. All of our product candidates developed from our iPSC allogeneic cell therapy platforms will require significant clinical and non-clinical development, review and approval by the FDA or other regulatory authorities in one or more jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before they can be successfully commercialized. If any of our product candidates encounter safety or efficacy problems, developmental delays, or regulatory issues or other problems, such problems could impact the development plans for our other product candidates because all of our product candidates are based on the same core iPSC technology.

Additionally, a key element of our strategy is to use and expand our iPSC allogeneic cell therapy platforms to build a pipeline of product candidates and progress those product candidates through clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have been focused on identifying a pipeline of product candidates, we may not be able to develop product candidates that a regulatory agency, such as the FDA, will consider safe and effective. Even if we are successful in building our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be approvable or marketable and achieve market acceptance. If we do not successfully develop, obtain approval for, and begin to commercialize any product candidates for which we receive approval, we will face difficulty in obtaining product revenue in future periods, which could result in significant harm to our financial position and adversely affect our share price.

Utilizing CAR-iNK and CAR-iT cells represents a novel approach to immuno-oncology treatment of cancer, and we must overcome significant challenges in order to develop, commercialize, and manufacture our product candidates.

We have concentrated our research and development efforts on developing CAR-iNK and CAR-iT cell therapies. The processes and requirements imposed by the FDA or other applicable regulatory authorities may cause delays and additional costs in obtaining approvals for our product candidates. Because our iPSC-derived allogeneic cell therapy platforms are novel, and cell-based therapies are relatively new, regulatory agencies may lack experience in evaluating our product candidates utilizing CAR-iNK and CAR-iT cells. This novelty may lengthen the regulatory review process, including the time it takes for the FDA to review our IND applications, if and when submitted, increase our development costs, and delay or prevent commercialization of our iPSC-derived allogeneic cell therapy platform products. Additionally, advancing novel immuno-oncology cell therapies creates significant challenges for us, including:

- developing and sustaining a manufacturing process to produce our cells on a large scale and in a cost-effective manner;
- educating medical personnel regarding the potential side-effect profile of our cells and, as the clinical program progresses, on any observed side effects with the therapy;
- unanticipated technical limitations of our CRISPR-MAD7 gene editing technology; and
- establishing sales and marketing capabilities, as well as developing a distribution network to support the commercialization of any approved products.

We must be able to overcome these challenges in order for us to successfully develop, commercialize, and manufacture our product candidates utilizing CAR-iNK and CAR-iT cells.

We have not yet demonstrated long-term stability of cryopreserved CAR-iNK cells.

We have not yet demonstrated long-term stability of cryopreserved CAR-iNK cells and, therefore, do not know if we will be able to store the cryopreserved cells for extended periods of time. If we are unable to demonstrate long-term stability, we will need to reduce the manufacturing batch size to ensure that the material we produce will be used before it expires. In that case, the scaling of our production processes will not deliver the efficiencies we expect, and the cost per dose of our product candidates will be substantially higher. We may also encounter difficulties not only in developing freezing and thawing methodologies for large-scale use, but also in obtaining the necessary regulatory approvals for using such methodologies in treatment. If we cannot adequately demonstrate similarity of our frozen product to the unfrozen form to the satisfaction of the FDA, we could face substantial delays in our regulatory approvals.

Gene-editing is a rapidly developing technology, and our success is dependent upon our ability to effectively utilize this technology in our product candidates and implement future technological advancements in gene-editing.

We use CRISPR-based nuclease to enable precise editing of the iPSC genome. For CNTY-101, we used the nuclease Cpf-1 but have shifted to CRISPR-MAD7 for all subsequent product candidates, and we may utilize CRISPR-MAD7 for CNTY-101 in the future. We decided to shift to CRISPR-MAD7 because we entered into a license agreement with Inscripta, Inc. and obtained a non-exclusive, royalty-free, irrevocable license to a patent portfolio covering the composition, production and use of CRISPR-MAD7. We have optimized the protocols to produce CRISPR-MAD7 and have achieved similar cutting and HDR efficiencies compared to Cpf-1, but we don't have as much experimental data with CRISPR-MAD7 as we do with Cpf1. We may encounter technical liabilities associated with CRISPR-MAD7 that could force us to use a different CRISPR nuclease which could delay our programs and require us to enter into a license agreement for additional technology, which may not be available on commercially reasonable terms or at all.

Our gene-editing technology may create unintended changes to the DNA such as a non-target site gene-edit, a large deletion, or a DNA translocation, any of which could impact timelines for new product generation. We have developed various genome characterization assays to identify deletions/insertions that can occur as a result of gene editing.

Although we believe CAR-iNK and CAR-iT based therapies do not require further modification to avoid the risk of graft versus host disease, or GvHD, the gene-editing of our product candidates utilizing CAR-iNK and CAR-iT cells may not be successful in limiting the risk of GvHD or premature rejection by patients.

In addition, the cell therapy industry is rapidly developing, and our competitors may introduce new gene-editing technologies that render our technology less attractive. Competitive pressures may force us to implement new gene-editing technologies at a substantial cost or delay in our clinical development process. In addition, our competitors may have greater financial, technical and personnel resources that allow them to implement new gene-editing technologies before we can. We cannot be certain that we will be able to implement new gene-editing technologies on a timely basis or at a cost that is acceptable to us. If we are unable to implement technological advancements consistent with industry standards, our operations and financial condition may be adversely affected.

Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Affordable Care Act, or the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or “biosimilar” product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of their product. 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. In addition, complexities associated with the larger, and often more complex, structures of biological products such as cell and gene products we are developing, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

We believe that any of our product candidates approved 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 our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our 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.

Jurisdictions in addition to the United States have established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier approved reference products. For example, the European Union has had an established regulatory pathway for biosimilars since 2004. However, biosimilars can only be authorized once the period of data exclusivity on the reference biological medicine has expired.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators’ market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our product candidates are approved for marketing, it is not possible to predict the length of market exclusivity for any particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues and we may not generate adequate or sufficient revenues from them or be able to reach or sustain profitability.

Preclinical and clinical development involve a lengthy and expensive process with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.

All but one of our product candidates are in preclinical development and the risk of failure for all of our product candidates is high. It is impossible to predict when or if any of our discovery or product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex, and expensive clinical trials that our product candidates are safe and effective in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process.

The results of preclinical studies and early clinical trials or early cohorts of our clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials or later cohorts of our clinical trials. Our initial clinical trials will begin with relatively small cohorts before expanding in size in subsequent cohorts. The initial cohorts of early-stage clinical trials often involve enrollment of a small number of patients and may not be as predictive as trials with larger cohorts. Additionally, if safety issues arise in an early cohort, we may be delayed or prevented from subsequently expanding into larger trial cohorts. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials.

Moreover, clinical data is often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. There is typically a high rate of failure of product candidates proceeding through clinical trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current clinical trials or future clinical trials, if allowed to proceed, will ultimately be successful or support clinical development of our current or any of our future product candidates.

We may experience delays in initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any of our current clinical trials or future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our lead product candidates or any future product candidates, including:

- regulators or institutional review boards, or IRBs, the FDA, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs as the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- clinical trials of any product candidates may fail to show safety or efficacy, produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;

- we may elect to, or regulators, IRBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;
- the cost of clinical trials of any of our product candidates may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be inadequate to initiate or complete a given clinical trial;
- our inability to manufacture sufficient quantities of our product candidates for use in clinical trials;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates;
- our failure to establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidate as well as data emerging from other studies or trials in the same class as our product candidate; and
- the FDA or applicable foreign regulatory agencies may require us to submit additional data such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the number and location of clinical sites we enroll, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the inability to obtain and maintain patient consents, the risk that enrolled participants will drop out before completion, competing clinical trials, and clinicians' patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or therapeutic biologics that may be approved for the indications being investigated by us, and other factors, such as the COVID-19 pandemic, over which we have no control. Furthermore, we are relying and expect to continue to rely on our collaborators, CROs, and clinical trial sites to ensure the proper and timely conduct of our current and future clinical trials, including the patient enrollment process, and we have limited influence over their performance. Additionally, we could encounter delays if treating physicians encounter unresolved ethical issues associated with enrolling patients in our current and future clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition, and results of operations significantly.

As an organization, we have limited experience designing and implementing clinical trials. Failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect the ability to initiate the trial, enroll patients, complete the trial, or obtain regulatory approval on the basis of the trial results, as well as lead to increased or unexpected costs.

The design and implementation of clinical trials is a complex process. While the employees who will implement our clinical trials have experience in the field, we, as an organization, have only recently initiated our first clinical trial. We have limited experience designing and no experience implementing clinical trials, and we may not successfully or cost-effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. A clinical trial that is not well designed may delay or even prevent initiation of the trial, can lead to increased difficulty in enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the study results, or, even if a product candidate is approved, could make it more difficult to commercialize the product successfully or obtain reimbursement from third-party payors. Additionally, a trial that is not well-designed could be inefficient or more expensive than it otherwise would have been, or we may incorrectly estimate the costs to implement the clinical trial, which could lead to a shortfall in funding.

Interim, topline, or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes 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 publicly disclose interim, topline, or preliminary data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Further, modifications or improvements to our manufacturing processes for a therapy may result in changes to the characteristics or behavior of the product candidate that could cause our product candidates to perform differently and affect the results of our ongoing clinical trials. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data has been received and fully evaluated. Topline data also remains subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data is available.

Preliminary or interim data from clinical trials is 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. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Additionally, disclosure of preliminary or interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate, and our company in general. If the interim, topline, or preliminary data that we report differs from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our potential product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

Beyond CNTY-101, we may not be able to file our INDs to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

We expect our pipeline to yield multiple additional INDs, including INDs for CNTY-102, CNTY-104, CNTY-106 and CNTY-107 product candidates from our iPSC-derived allogeneic cell therapy platforms. We cannot be sure that submission of an IND will result in the FDA allowing testing and clinical trials to begin, or that, once begun, issues will not arise that result in suspension or termination of such clinical trials. The manufacturing of our product candidates remains an emerging and evolving field. Accordingly, we expect chemistry, manufacturing and control related topics, including product specifications, will be a focus of IND reviews, and unfavorable findings may delay or prevent the FDA from allowing us to proceed with clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, or CTA, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

We are pursuing multiple programs and product candidates in our novel cell therapy development pipeline using an approach that is designed to enable rapid incorporation of new product features. If we elect to incorporate these new features into next-generation product candidates, this may render our existing product candidates obsolete, and we may devote our limited resources in pursuit of a particular program for which there is a greater potential for success and fail to capitalize on development opportunities or product candidates including those which may be more advanced in development.

We focus on the development of programmed cellular immunotherapies for patients with cancer, including off-the-shelf NK- and T-cell product candidates derived from clonal master engineered iPSC lines. Because our iPSC-derived allogeneic cell therapy platforms are designed to enable rapid incorporation of novel functional product features in an evolving clinical setting, we may elect to incorporate these discoveries into next-generation product candidates that render our existing product candidates, including product candidates under clinical development, obsolete. Additionally, because we have limited financial and personnel resources, we may elect or be required to abandon or delay the pursuit of opportunities with existing or future product candidates, including those that may be more advanced in development than those we ultimately elect to pursue. Due to these factors, our spending on current and future research and development programs and product candidates and the scientific innovation arising from these expenditures may not yield commercially viable product candidates.

We intend to study our product candidates in patient populations with significant comorbidities that may result in deaths or serious adverse events or unacceptable side effects and require us to abandon or limit our clinical development activities.

Patients we intend to treat with our product candidates may also receive chemotherapy, radiation, and/or other cell therapy treatments in the course of treatment of their disease, and may therefore experience side effects or adverse events, including death, that are unrelated to our product candidates. While these side effects or adverse events may be unrelated to our product candidates, they may still affect the success of our clinical studies. The inclusion of critically ill patients in our clinical studies may result in deaths or other adverse medical events due to underlying disease or to other therapies or medications that such patients may receive. Any of these events could prevent us from advancing our product candidates through clinical development, and from obtaining regulatory approval, and would impair our ability to commercialize our product candidates, if approved. Any inability to advance our existing product candidates or any other product candidate through clinical development would have a material adverse effect on our business.

We may experience difficulties identifying and enrolling patients in our clinical trials. Difficulty in enrolling patients could delay or prevent clinical trials of CNTY-101 or our other product candidates.

Identifying and qualifying patients to participate in clinical trials of CNTY-101 is critical to our success. The timing of our clinical trials depends in part on the speed at which we can recruit patients to participate in testing CNTY-101, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. The eligibility criteria of our clinical trials may limit the pool of available study participants as it will require patients to have specific characteristics that we can measure to ensure their disease is either severe enough or not too advanced to include them in a clinical trial. The process of finding and diagnosing patients may prove costly. We also may not be able to identify, recruit, and enroll a sufficient number of appropriate patients to complete our clinical trials because of demographic criteria for prospective patients, the perceived risks and benefits of the product candidate under study, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. The availability and efficacy of competing therapies and clinical trials can also adversely impact enrollment. If patients are unwilling to participate in our trials for any reason, the timeline for recruiting patients, conducting trials, and obtaining regulatory approval of potential products may be delayed, the commercial prospects of CNTY-101 or our other product candidates will be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. Furthermore, our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs and jeopardize our ability to achieve our clinical development timeline and goals, including the dates by which we will commence, complete, and receive results from clinical trials. Enrollment delays in our clinical trials may also jeopardize our ability to commence sales of and generate revenues from CNTY-101 or our other product candidates. Any of these occurrences may harm our business, financial condition, and prospects significantly.

CNTY-101 and our other product candidates may cause adverse events or undesirable side effects that could delay or prevent its regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Cell therapy is still a relatively new approach to disease treatment and adverse side effects could develop. There also is the potential risk of delayed adverse events following exposure to cell therapy products due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material.

We have been collecting data about CNTY-101 in preclinical studies and will continue to do so in clinical trials including Elipse-1. We began dosing patients in February 2023 in our Elipse-1 clinical trial. Prior to the first-in-human study, we have only evaluated CNTY-101 in preclinical mouse models and we therefore do not know the side effect profile of our products in humans. Accordingly, we may experience unexpected side effects and/or higher levels of known side effects in clinical trials, including adverse events known in cell therapies. These include the potential for, among others, cytokine release syndrome, or CRS, and neurotoxicity, or immune effector cell-associated neurotoxicity syndrome. B-cell directed therapies may also demonstrate infusion reactions/hypersensitivity, serious infections, prolonged cytopenias, hypogammaglobulinemia/B-cell aplasia, and secondary malignancies.

Any adverse events or undesirable side effects caused by, or other unexpected properties of, CNTY-101 or our other product candidates could cause us, any future collaborators, an IRB, or ethics committee or regulatory authorities to interrupt, delay, or halt clinical trials of our product candidates and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. It is possible that as we progress CNTY-101 or our other product candidates through preclinical and clinical development, or as the use of CNTY-101 or our other product candidates become more widespread if it receives regulatory approval, illnesses, injuries, discomforts, and other adverse events that were not observed in preclinical studies or clinical trials, as well as conditions that did not occur or went undetected, will be reported by patients. If such side effects become known later in development or after approval, such findings may harm our business, financial condition, and prospects significantly. Further, if a serious safety issue is identified in connection with the use of CNTY-101 or our other product candidates commercially or in third-party clinical trials elsewhere, such issues may adversely affect the development potential of CNTY-101 or our other product candidates or result in regulatory authorities restricting our ability to develop or commercialize CNTY-101 or our other product candidates.

Further, if CNTY-101 or any of our other product candidates were to receive regulatory approval and we or others identify undesirable side effects caused by the product (or any other product) after the approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may request that we recall or withdraw the product from the market or may limit the approval of the product through labeling or other means;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication or a precaution;
- we may be required to change the way the product is distributed or administered, conduct additional clinical trials, or change the labeling of the product;
- we may decide to recall or remove the product from the marketplace;
- we could be sued and/or held liable for injury caused to individuals exposed to or taking our product candidates;
- damage to the public perception of the safety of CNTY-101 or our other product candidates; and

- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates and significantly impact our ability to successfully commercialize our product candidates, if approved, and generate revenues, all of which would materially adversely affect our business, financial condition, and results of operations.

Public opinion and scrutiny of cell-based immuno-oncology therapies for treating cancer, or negative clinical trial results from our cell-based therapy competitors, may impact public perception of our company and product candidates, or impair our ability to conduct our business.

Our iPSC-derived allogeneic cell therapy platforms utilize a relatively novel technology involving the genetic modification of iPSC's and utilization of those modified cells in other individuals, and no iNK cell-based immunotherapy has been approved to date. Public perception may be influenced by claims, such as claims that cell-based immunotherapy is unsafe, unethical, or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to cell-based immunotherapy in general, or negative clinical trial results from our cell-based therapy competitors, could result in greater government regulation and stricter labeling requirements of cell-based immunotherapy products, including any of our product candidates, and could cause a decrease in the demand for any products we may develop. Adverse public attitudes may adversely impact our ability to enroll clinical trials. More restrictive government regulations or negative public opinion could have an adverse effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by lobbying for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed, or become more expensive.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our product candidates, if approved, may be delayed.

From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory, manufacturing and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of preclinical studies and clinical trials and the submission of regulatory filings, including IND and BLA submissions. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are, and will be, based on a variety of assumptions. The actual timing of these milestones can vary significantly compared to our estimates, in some cases for reasons beyond our control. We may experience numerous unforeseen events during, or as a result of, any clinical trials that we conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates.

Changes in regulatory requirements, guidance from the FDA and other regulatory authorities, or unanticipated events during our clinical trials of CNTY-101 or our other product candidates may result in changes to preclinical studies or clinical trials or additional preclinical or clinical trial requirements, which could result in increased costs to us and could delay our development timeline.

Regulatory requirements governing biologic drug products, including cell therapy products, are still evolving and it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for CNTY-101 or our other product candidates. Changes in regulatory requirements, FDA guidance or guidance from other regulatory agencies, or unanticipated events during our preclinical studies or clinical trials may force us to terminate or adjust our development program.

In addition, the clinical trial requirements of the FDA and foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, intended use, and market of such product candidates. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or more extensively studied product candidates. The FDA, or the applicable regulatory authorities, may impose additional preclinical or clinical trial requirements. Amendments to clinical trial protocols would require resubmission to the FDA, or the applicable regulatory authorities as well as IRBs and ethics committees for review and approval, which may adversely impact the cost, timing, or successful completion of a clinical trial. If we experience delays completing, or if we terminate, any of our clinical trials, or if we are required to conduct additional preclinical or clinical trials, the commercial prospects for CNTY-101 or our other product candidates may be harmed and our ability to generate product revenue will be delayed, and it would materially adversely affect our business, financial condition, and results of operations.

In order to market any product outside of the United States, we must comply with numerous and varying regulatory requirements of other countries regarding biologic development and commercialization. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being advanced, developed, cleared or approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products or regulatory submissions can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies 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 or modifications to cleared or approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the United States government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections at domestic and foreign manufacturing facilities from March 2020 until July 2021. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates, and any resurgence of the virus may lead to further inspectional delays. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, 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.

We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials for our product candidates.

We rely on third-party CROs, study sites, and others to conduct, supervise, and monitor our preclinical studies and clinical trials for our product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials of our product candidates. Although we have agreements with these third parties governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines, could substantially harm our business because we may be delayed in completing or unable to complete the preclinical studies and clinical trials required to support future approval of CNTY-101 and our other product candidates, or we may not obtain marketing approval for, or commercialize, CNTY-101 and our other product candidates in a timely manner or at all. Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities would be delayed and our business, financial condition, results of operations, and prospects may be materially harmed.

Our reliance on these third parties for development activities reduces our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols for such trial. We must also ensure that our preclinical studies and clinical trials are conducted in accordance with cGLP regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with cGCPs for conducting, recording, and reporting the results of clinical trials to ensure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable cGCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, or comparable foreign regulatory authorities may require us to perform additional studies.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials will comply with the applicable regulatory requirements. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations.

Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, www.clinicaltrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

The third parties with which we work may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. In addition, such third parties are not 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 developmental and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if these parties are adversely impacted by macroeconomic or other factors limiting or materially affecting their ability to carry out their contractual duties, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our preclinical studies and clinical trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for CNTY-101 and our other product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize CNTY-101 or our other product candidates; or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for CNTY-101 and our other candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business, financial condition, results of operations, and prospects may be materially harmed.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management's time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms, and product candidates that we identify for specific indications. As a result, we may forego or delay our pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential. 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, therapeutic platforms, and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights, including intellectual property rights, to that product 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.

We are party to a Collaboration Agreement with Bristol-Myers Squibb, and pursuant to the terms of that agreement, could become dependent on Bristol-Myers Squibb for development and commercialization activities with respect to certain of our product candidates.

We are party to a Research, Collaboration and License Agreement with Bristol-Myers Squibb, or the Collaboration Agreement, pursuant to which we agreed to collaborate on the research, development and commercialization of iNK and iT cell programs for hematologic malignancies and solid tumors. Pursuant to the Collaboration Agreement, Bristol-Myers Squibb will initially collaborate with us on two collaboration programs

and has the option to add up to two additional collaboration programs, for an additional fee. We are responsible for generating development candidates for the collaboration programs with Bristol-Myers Squibb. Once a development candidate meets certain criteria, Bristol-Myers Squibb has the option to exclusively license the development candidates for pre-clinical development, clinical development and commercialization on a worldwide basis. Upon the exercise by Bristol-Myers Squibb of its option for a development candidate, Bristol-Myers Squibb will be responsible for all regulatory, clinical, manufacturing (after a proof of concept clinical trial) and commercialization activities with respect to that development candidate, subject to the terms of the Collaboration Agreement. Bristol-Myers Squibb may elect not to exercise its option and we may not obtain all the intellectual property rights required to develop the product candidates on our own. We cannot control whether Bristol-Myers Squibb will devote sufficient attention or resources to this collaboration or will proceed in an expeditious manner. Even if the FDA or other regulatory agencies approve any of the licensed product candidates, Bristol-Myers Squibb may elect not to proceed with the commercialization of the resulting product in one or more countries.

Under the Collaboration Agreement, Bristol-Myers Squibb paid us an upfront payment of \$100 million. In addition to the upfront payment, we may receive development and regulatory milestone payments of up to an additional \$235 million. We will also be eligible to receive up to an additional \$500 million in payments upon the achievement of certain sales milestones. We will also be entitled to receive, subject to certain reductions, tiered royalties ranging from high-single digits up to low-teens as percentages net sales, if any, on any licensed product generated pursuant to the Collaboration Agreement. The milestones that trigger a payment or royalties under the Collaboration Agreement may never be reached and failure to do so could harm our business and financial condition.

Bristol-Myers Squibb has customary rights to terminate the Collaboration Agreement and if Bristol-Myers Squibb terminates the Collaboration Agreement, it will result in a delay in or could prevent us from developing or commercializing the product candidates subject to the Collaboration Agreement. Further, disputes may arise between us and Bristol-Myers Squibb, which may delay or cause the termination of this collaboration, result in significant litigation, cause Bristol-Myers Squibb to act in a manner that is not in our best interest or cause us to seek another collaborator or proceed with development, commercialization and funding on our own. If we seek a new collaborator but are unable to do so on acceptable terms, or at all, or do not have sufficient funds to conduct the development or commercialization of such development candidates we may have to curtail or abandon that development or commercialization, which could harm our business.

We may explore strategic collaborations that may never materialize or we may be required to relinquish important rights to and control over the development and commercialization of our product candidates to any future collaborators.

Our business strategy includes leveraging our strategic partnership with Bristol-Myers Squibb and FUJIFILM Cellular Dynamics Inc., or FCDI, and may include additional future partnerships for product development, product commercialization, manufacturing or other strategic objectives. As a result, we may in the future determine to collaborate with additional companies for development and potential commercialization of one or more therapeutic products. At the current time however, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations can be complicated and time-consuming to negotiate and document.

We may not be able to negotiate strategic collaborations on acceptable terms, if at all. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake

development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our technology platforms and our business may be materially and adversely affected.

If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. We are unable to predict when, if ever, we will enter into any strategic partnerships because of the numerous risks and uncertainties associated with establishing them, including:

- expenditure of substantial operational, financial and management resources;
- dilutive issuances of our securities;
- substantial actual or contingent liabilities; and
- termination or expiration of the arrangement, which would delay the development and may increase the cost of developing our product candidates.

Strategic partners may also delay clinical trials, experience financial difficulties, provide insufficient funding, terminate a clinical trial, or abandon a product candidate, which could negatively impact our development efforts. Additionally, strategic partners may not properly maintain, enforce, or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation, any of which could adversely affect our business, financial position, and operations.

If our collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. All of the risks relating to product development, regulatory approval, and commercialization described in this Annual Report on Form 10-K also apply to the activities of our program collaborators. Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination, the collaborator may deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If our collaborator terminates its agreement with us, it may find it more difficult to attract new collaborators.

Risks related to manufacturing

The manufacture and distribution of our iPSC-derived cell product candidates is complex and subject to a multitude of risks. These risks could substantially increase our costs and limit the clinical and commercial supply of our product candidates.

The manufacture and supply of our product candidates involve novel processes that are more complex than those required for most drugs, biologics and other cellular immunotherapies and, accordingly, present significant challenges and are subject to multiple risks. These complex processes include reprogramming human somatic cells to obtain iPSCs, genetically engineering these iPSCs, and differentiating the iPSCs to obtain the desired product candidate. As a result of the complexities in manufacturing biologics and distributing cell therapies, the cost to manufacture and distribute biologics and cell therapies in general, and our cell product candidates in particular, is generally higher than traditional small molecule chemical compounds. In addition, our cost of goods development is at an early stage. The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates.

We have limited experience in the manufacture of cell-based therapies. We are still developing optimized and reproducible manufacturing processes for clinical and commercial-scale manufacturing of our product candidates, and none of our manufacturing processes have been validated for commercial production of our product candidates. In addition, we are still optimizing our protocols for the supply and transport of our product candidates for distribution to clinical trial sites. Although we are working to develop reproducible and commercially viable manufacturing processes for our product candidates, and effective protocols for the supply and transport of our product candidates, doing so is a difficult and uncertain task.

We may make changes as we continue to develop and refine the manufacturing and distribution processes for our product candidates for clinical trials and commercialization, and we cannot be sure that even minor changes in these processes will not cause our product candidates to perform differently and affect the results of our ongoing and planned clinical trials or the performance of the product once commercialized. In some circumstances, changes in our manufacturing operations, including to our protocols, processes, materials, or facilities used, may require us to perform additional preclinical or comparability studies, or to collect additional clinical data from patients prior to undertaking additional clinical studies or filing for regulatory approval for a product candidate. These requirements may lead to delays in our clinical development and commercialization plans for our product candidates, and may increase our development costs substantially.

Cell-based therapies depend on the availability of reagents and specialized materials and equipment which in each case are required to be acceptable to the FDA and foreign regulatory agencies, and such reagents, materials, and equipment may not be available to us on acceptable terms or at all. We rely on third-party suppliers for various components, materials, and equipment required for the manufacture of our product candidates and do not have supply arrangements for certain of these components.

Manufacturing our product candidates requires many reagents and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. To date, we and our clinical cell processing facilities and CMOs have purchased equipment, materials, and disposables, such as automated cell washing devices, automated cell warming units, commercially available media, and cell transfer and wash sets, used for the manufacture of our existing product candidates from third-party suppliers. Some of these suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. Reagents and other key materials from these suppliers may have inconsistent attributes and introduce variability into our manufactured product candidates, which may contribute to variable patient outcomes and possible adverse events. We rely on the general commercial availability of materials required for the manufacture of our product candidates, and do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Even if we are able to enter into such contracts, we may be limited to a sole third party for the supply of certain required components, including our pharmacologic modulators and components for our cell processing media. As a result of the lingering effects of the recent COVID-19 pandemic and other factors, the business and operations of our suppliers may be disrupted or delayed, and we in turn may experience disruptions or delays in our supply chain. An inability to continue to source product from any of these suppliers, which could be due to the impacts of global pandemics, macroeconomic factors, recent regulatory actions, or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

If we are required to change suppliers, or modify the components, equipment, materials, or disposables used for the manufacture of our product candidates, we may be required to change our manufacturing operations or clinical trial protocols or to provide additional data to regulatory authorities in order to use any alternative components, equipment, materials, or disposables, any of which could set back, delay, or increase the costs required to complete our clinical development and commercialization of our product candidates. Additionally, any such change or modification may adversely affect the safety, efficacy, stability, or potency of our product candidates, and could adversely affect our clinical development of our product candidates and harm our business.

We rely on third parties for the manufacture of some of our product candidates for development, and we are beginning to operate our own manufacturing facility for the production of certain of our product candidates.

We are now operating our own manufacturing facilities and but still rely on FCDI for the manufacture of some of our product candidates and CMOs for the manufacture of related raw materials for clinical and preclinical development. It is uncertain whether we will be able to utilize our own manufacturing facilities for commercial manufacturing of our products and therefore, we may need to rely on third parties for commercial manufacturing if any of our product candidates receive marketing approval. We have partnered with FCDI for the manufacture and supply of some of our product candidates for future clinical development, as well as to establish commercial supplies of our product candidates, if approved. If either of our Manufacturing Agreement or Master Collaboration Agreement with FCDI terminates, and if we need to enter into alternative arrangements, our product development activities could be delayed and our business, financial condition, results of operations, and prospects may be materially harmed. We completed construction of our own 53,000 square foot cGMP manufacturing facility in Branchburg, New Jersey as well as the fit-out and qualifications for the facility in 2022 and the facility is operational. However, we are only beginning to gain operational experience in the facility and there can be no assurance that we will be able to reliably manufacture our product candidates in this facility in a timely manner, or at all.

The facilities used by us, FCDI, and any other manufacturers with which we may collaborate must be approved by the FDA pursuant to inspections that will be conducted after we submit a BLA to the FDA. For manufacturing facilities in which we do not operate, we do not control the manufacturing process of, and are completely dependent on, CMOs for compliance with cGMP requirements for the manufacture of biologic products. If these CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of CMOs to maintain adequate quality control, quality assurance, and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Our failure, or the failure of our CMO, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

Our or a CMO's failure to execute on our manufacturing requirements, to do so on commercially reasonable terms and comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of CNTY-101 or our other product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates;

- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize CNTY-101 or our other product candidates, an inability to meet commercial demands for CNTY-101 or our other product candidates.

Any performance failure on the part of us or our existing or future CMOs could delay clinical development or marketing approval, and any related remedial measures may be costly or time-consuming to implement. If our current CMOs cannot perform as agreed or if our own cGMP manufacturing facility in Branchburg, New Jersey does not operate as expected, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all.

Our current and anticipated future dependence upon CMOs for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Delays in commissioning and receiving regulatory approvals for our manufacturing facilities could delay our development plans and thereby limit our ability to generate revenues.

We believe that internal cGMP manufacturing is important to facilitate clinical product supply, lower the risk of manufacturing disruptions, and enable more cost-effective manufacturing. We believe our Branchburg, New Jersey facility will allow us to supply certain of our product candidates needed for our early-stage clinical trials and preclinical studies. The operation and maintenance, and regulatory approvals for such facilities, require substantial capital and technical expertise and any delay could limit our development activities and our opportunities for growth, or negatively impact our financial results.

Furthermore, our manufacturing facility will be subject to ongoing, periodic inspection by the FDA and other comparable regulatory agencies to ensure compliance with cGMP. Our failure to follow and document our adherence to these regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical use or may result in the termination of or a hold on a clinical study. Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions, and criminal prosecutions, any of which could materially adversely affect our business, financial condition, results of operations, and growth prospects.

We also may encounter problems with the following:

- complying with regulations regarding donor traceability, manufacturing, release of product candidates and other requirements from regulatory authorities outside the United States;
- achieving adequate or clinical-grade materials that meet regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- bacterial, fungal, or viral contamination in our manufacturing facility; and
- shortages of qualified personnel, raw materials, or key contractors.

Our product candidates, if approved by applicable regulatory authorities, may require significant commercial supply to meet market demand. In these cases, we may need to increase, or “scale up,” the production process by a significant factor over the initial level of production. If we fail to develop sufficient manufacturing

capacity and experience, whether internally or with a third party, are delayed in doing so, or fail to manufacture our product candidates economically or on reasonable scale or volumes, or in accordance with cGMP, or if the cost of this scale-up is not economically feasible, our development programs and commercialization of any approved products will be materially adversely affected and we may not be able to produce our product candidates in a sufficient quantity to meet future demand and our business, financial condition, results of operations, and growth prospects may be materially adversely affected.

We cryogenically store our CAR-iNK and CAR-iT cells and master and working cell banks of the engineered iPSC cells at both our own manufacturing facility and at third party facilities

The CAR-iNK and CAR-iT cells and the master and working cell banks of the engineered iPSC cells are stored in freezers at both third-party biorepositories and in our freezers at our manufacturing facility. If these materials are damaged at either or both our or these third party facilities, including by the loss or malfunction of these freezers or our back-up power systems, as well as by damage from fire, power loss or other natural disasters, we may need to establish replacement CAR-iNK and CAR-iT cells and master and working cell banks of the engineered iPSC cells, which would impact clinical supply and delay patient treatment. If we are unable to establish replacement materials, we could incur significant additional expenses and liability to patients whose treatment is delayed, and our business could suffer.

Risks related to commercialization of our product candidates

If we are unable to successfully commercialize CNTY-101 or any of our other product candidates for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.

If we are successful in obtaining marketing approval from applicable regulatory authorities for CNTY-101 or any of our other product candidates, our ability to generate revenues from such product candidates will depend on our success in:

- launching commercial sales of our product candidates, whether alone or in collaboration with others;
- receiving an approved label with claims that are necessary or desirable for successful marketing, and that does not contain safety or other limitations that would impede our ability to market our product candidates;
- creating market demand for our product candidates through marketing, sales, and promotion activities;
- hiring, training, and deploying a sales force or contracting with third parties to commercialize our product candidates;
- manufacturing, either on our own or through third parties, product candidates in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;
- creating partnerships with, or offering licenses to, third parties to promote and sell product candidates in foreign markets where we receive marketing approval;
- obtaining, maintaining, protecting, and enforcing patent and trade secret protection and regulatory exclusivity for our product candidates;

- achieving market acceptance of our product candidates by patients, the medical community, and third-party payors;
- achieving appropriate reimbursement for our product candidates, if approved;
- effectively competing with other therapies; and
- maintaining an acceptable tolerability profile of our product candidates following launch.

To the extent we are not able to do any of the foregoing, our business, financial condition, results of operations, and prospects will be materially harmed.

We face significant competition, and if our competitors develop product candidates more rapidly than we do or their product candidates are more effective, our ability to develop and successfully commercialize products may be adversely affected.

The biopharmaceutical and pharmaceutical industries are characterized by rapid innovation, intense and dynamic competition and a strong emphasis on proprietary and novel products and product candidates. While we believe that our technology, scientific knowledge, and experience in the field of cellular immunotherapy provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biopharmaceutical companies, academic institutions, governmental agencies, and public and private research institutions, as well as standard-of-care treatments, and new products undergoing development and combinations of existing and new therapies. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies, including combinations thereof, that may become available in the future. We compete with these organizations to recruit management, scientists, and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials, and in identifying and in-licensing new product candidates. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We are developing off-the-shelf cell therapies by differentiating engineered iPSC into NK-, T-, or other immune cells for the treatment of various cancers. While we believe our genetically-engineered immune effector cell therapies derived from iPSC are highly differentiated, a number of companies are currently focused on the development of cellular immunotherapies for the treatment of cancer. In addition, because reprogramming technology and gene editing technology are available on a non-exclusive basis, the number of companies developing iPSC-derived products and products using gene editing technology is expected to increase, which will increase competitive pressure on us. Moreover, the reprogramming technology licensed to us from FCDI and the gene editing technology licensed to us from Inscripta, Inc. are each licensed to us on a non-exclusive basis, and therefore third parties may obtain licenses to the same technology to compete with us.

Large pharmaceutical companies that have commercialized or are developing immunotherapies to treat cancer include AstraZeneca, Bristol-Myers Squibb, Gilead Sciences, Merck, Novartis, Pfizer, and Roche/Genentech. Companies that compete with us directly on the level of the development of product candidates targeting B-cell lymphomas include Gilead Sciences, Novartis, Roche, Genmab, Abbvie and Bristol-Myers Squibb, among others. On the technology level, other emerging biopharmaceutical companies which can potentially develop competing cell therapy candidates to treat cancer include Fate Therapeutics, Allogene Therapeutics, CRISPR Therapeutics, Caribou Biosciences, Shoreline Biosciences, Sana Biotechnology and Nkarta Therapeutics.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales, and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage, and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive, or marketed and sold more effectively than any products we may develop. Our competitors also may obtain FDA or other regulatory approval for their products 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. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

We expect to face uncertainty regarding the pricing of our existing product candidates and any other product candidates that we may develop, and for which we may receive approval.

Due to the novel nature of our product candidates, we face significant uncertainty as to the pricing of any such products for which we may receive marketing approval. While we anticipate that pricing for any product candidates that we develop will be relatively high due to their anticipated use in the prevention or treatment of life-threatening diseases where therapeutic options are limited, the biopharmaceutical industry has recently experienced significant pricing pressures, including in the area of orphan drug products. In particular, drug pricing and other healthcare costs continue to be subject to intense political and societal pressures, which we anticipate will continue and escalate on a global basis. These pressures may result in harm to our business and reputation, cause our stock price to decline or experience periods of volatility, and adversely affect results of operations and our ability to raise funds.

In addition, we expect to experience pricing pressures in connection with the pricing of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new products could limit our product revenues.

Our ability to commercialize any of our product candidates successfully will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. In the United States, the principal decisions about reimbursement for new therapies are typically made by Centers for Medicare and Medicaid

Services, or CMS, an agency within the United States Department of Health and Human Services. CMS decides whether and to what extent a new therapy will be covered and reimbursed under Medicare, and private payors tend to follow CMS determinations to a substantial degree. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments, such as cellular immunotherapy. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products by government and third-party payors. In particular, there is no body of established practices and precedents for reimbursement of cellular immunotherapies, and it is difficult to predict what the regulatory authority or private payor will decide with respect to reimbursement levels for novel products such as ours. Our products may not qualify for coverage or direct reimbursement, or may be subject to limited reimbursement. If reimbursement or insurance coverage is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates, if approved. Even if coverage is provided, the approved reimbursement amount may not be sufficient to allow us to establish or maintain pricing to generate income.

In addition, reimbursement agencies in foreign jurisdictions may be more conservative than those in the United States. Accordingly, in markets outside the United States, the reimbursement for our product candidates, if approved, may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits. Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved, and as a result, they may not cover or provide adequate payment for our product candidates. Failure to obtain or maintain adequate reimbursement for any products for which we receive marketing approval will adversely affect our ability to achieve commercial success, and could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

Even if we obtain regulatory and marketing approval for a product candidate, our product candidates will remain subject to regulatory oversight.

Even if we receive marketing and regulatory approval for CNTY-101 or any of our other product candidates, regulatory authorities may still impose significant restrictions on the indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. CNTY-101 and our other product candidates will also be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, and submission of safety and other post-market information. The FDA has significant post-market authority, including, for example, the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate serious safety risks related to the use of a biologic. Any regulatory approvals that we receive for CNTY-101 or our other product candidates may also be subject to a risk evaluation and mitigation strategy, or REMS, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including post-approval clinical trials, and surveillance to monitor the quality, safety, and efficacy of the product, all of which could lead to lower sales volume and revenue. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover(s) previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the

market or suspension of manufacturing. Additionally, under FDORA, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed.

If we or our contractors fail to comply with applicable regulatory requirements following approval of CNTY-101 or our other product candidates, a regulatory authority may:

- issue a warning letter, untitled letter, or Form 483, asserting that we are in violation of the law;
- request voluntary product recalls;
- seek an injunction or impose administrative, civil, or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto);
- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise require the withdrawal of the product from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize CNTY-101 or our other product candidates and adversely affect our business, financial condition, results of operations, and prospects.

Even if we receive marketing approval for CNTY-101 or our other product candidates, we may not achieve broad market acceptance.

The commercial success of CNTY-101 or our other product candidates, if developed and approved for marketing by the FDA or comparable foreign regulatory authority, will depend upon the awareness and acceptance of CNTY-101 or such other product candidate among the medical community, including physicians, patients, advocacy groups, and healthcare payors. Market acceptance of our product candidates, if approved, will depend on a number of factors, including, among others:

- the prevalence and severity of any adverse side effects associated with our product candidates;
- limitations or warnings contained in the labeling approved for our product candidates by the FDA or comparable foreign regulatory authority, such as a "black box" warning;
- availability of alternative treatments, including any competitive therapies in development that could be approved or commercially launched prior to approval of our product candidates;

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- pricing;
- payor acceptance;
- the impact of any future changes to the United States healthcare system;
- the effectiveness of our sales and marketing strategies; and
- the likelihood that the FDA may require development of a REMS, as a condition of approval or post-approval or may not agree with our proposed REMS or may impose additional requirements that limit the promotion, advertising, distribution, or sales of our product candidates.

If CNTY-101 or any of our other product candidates are approved but do not achieve an adequate level of acceptance by patients, advocacy groups, physicians and payors, we may not generate sufficient revenue to become or remain profitable and our business, financial condition, and results of operations could be materially adversely affected. Our efforts to educate the medical community and third-party payors about the benefits of CNTY-101 and our other product candidates may require significant resources and may never be successful.

Even if we receive marketing approval for CNTY-101 or our other product candidates in the United States, we may never receive regulatory approval to market CNTY-101 or our other product candidates outside of the United States.

In order to market any product outside of the United States, we must establish and comply with the numerous and varying safety, efficacy, and other regulatory requirements of other jurisdictions, including potential additional clinical trials and/or preclinical studies. Approval procedures vary among jurisdictions and can involve additional testing and additional administrative review periods. The time required to obtain approvals in other jurisdictions might differ from that required to obtain FDA approval. The marketing approval processes in other jurisdictions may implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many jurisdictions outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such jurisdictions. Marketing approval in one jurisdiction does not necessarily ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process or commercial activities in others. Failure to obtain marketing approval in other jurisdictions or any delay or other setback in obtaining such approval would impair our ability to market a product candidate in such foreign markets. Any such impairment would reduce the size of our potential market, which could have a material adverse impact on our business, financial condition, results of operations, and prospects.

We may be unable to establish effective marketing, sales and distribution capabilities or enter into agreements with third parties to market and sell CNTY-101 or our other product candidates, if approved.

We currently do not have a commercial infrastructure for the marketing, sale, and distribution of CNTY-101, or our other product candidates. If CNTY-101 or our other product candidates receive marketing approval, we intend to commercialize such product candidates in the United States and potentially in other geographies. In order to commercialize our products, we must build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services. We may not be successful in doing so. Should we

decide to move forward in developing our own marketing capabilities, we may incur expenses prior to product launch or even approval in order to recruit a sales force and develop a marketing and sales infrastructure. If a commercial launch is delayed as a result of the FDA's or comparable foreign regulatory authority's requirements or for other reasons, we would incur these expenses prior to being able to realize any revenue from sales of CNTY-101 and our other product candidates. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing CNTY-101 or our other product candidates. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may also or alternatively decide to collaborate with third-party marketing and sales organizations to commercialize any approved product candidates in the United States, in which event, our ability to generate product revenues may be limited. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts, and could be held liable if they failed to comply with applicable legal or regulatory requirements.

We have no prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in building and managing a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products we may develop will be expensive and time-consuming and could delay any product launch, and we may not be able to successfully develop this capability. We will have to compete with other biopharmaceutical and pharmaceutical companies to recruit, hire, train, manage, and retain marketing and sales personnel, which is expensive and time-consuming and could delay any product launch. Developing our sales capabilities may also divert resources and management attention away from product development.

In the event we are unable to develop a marketing and sales infrastructure, we may not be able to commercialize CNTY-101 or our other product candidates, if approved, in the United States or elsewhere, which could limit our ability to generate product revenues and materially harm our business, financial condition, results of operations, and prospects.

If the market opportunities for our product candidates for which we receive marketing approval are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

Cancer therapies are sometimes characterized as first-line, second-line, or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy, or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. Initial planned clinical trials are expected to enroll patients who have received other available therapies in order to first evaluate whether the product is safe and whether there is any activity. Although we have initiated our first clinical trial of CNTY-101 in patients that have received prior lines of therapy, we have limited data, to date, on the side effect profile of our product candidate in humans and we do not know at this time whether any of our other product candidates will be safe for use in humans or whether they will demonstrate any anti-cancer activity. Subsequently, we plan to conduct additional clinical trials depending on the activity we note in the initial clinical trials. If the activity is sufficient, we may initially seek approval of any product candidates we develop as a therapy for patients who have received one or more prior treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially in earlier lines of therapy, but there is no guarantee that product candidates we develop, even if approved for later lines of therapy, would be approved for earlier lines of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

We focus our research and product development on differentiating engineered iPSC into NK-, T-, or other immune cells for the treatment of various cancers. Our projections of both the number of people who have

these cancers, as well as the subset of people with these cancers who have the potential to benefit from treatment with our product candidates, are based on beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new trials may change the estimated incidence or prevalence of such cancers. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost, and efficacy of our product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug and biologic pricing, and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates, for which we receive marketing approval, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing and cost of, and level of investment in, research, development, regulatory approval, and commercialization activities relating to CNTY-101 and our other product candidates, which may change from time to time;
- coverage and reimbursement policies with respect to CNTY-101 and our other product candidates, if approved, and potential future drugs or biologics that compete with our products;
- the cost of manufacturing CNTY-101 and our other product candidates, which may vary depending on the quantity of production and the terms of our agreements with CMOs;
- the timing and amount of the milestone or other payments we must make to the licensors and other third parties from whom we have in-licensed or acquired our product candidates;
- the level of demand for any approved products, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies; and
- any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

Risks related to employee matters, managing growth and other risks related to our business

We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain, and motivate highly qualified management, clinical, and scientific personnel, many of whom have been instrumental for us and have substantial experience with our iPSC-derived allogeneic cell therapy platforms, underlying technologies, and related product candidates. Given the specialized nature of our iPSC-derived allogeneic cell therapy platforms and the fact that ours is a novel and emerging field, there is an inherent scarcity of experienced personnel in this field. As we continue developing our product candidates in our pipeline, we will require personnel with medical, scientific, or technical qualifications specific to each program.

We are highly dependent upon our senior management, particularly Osvaldo Flores, Ph.D., our Chief Executive Officer, as well as our senior scientists and other members of our executive team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our planned clinical trials, or the commercialization of CNTY-101 and our other product candidates. We have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

Our research and development programs, clinical operations, and sales and marketing efforts depend on our ability to attract and retain highly skilled scientists, engineers, and sales professionals. The competition for qualified personnel in the biotechnology and pharmaceutical industries is intense, and we have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel have greater resources than we do, and any of our employees may terminate their employment with us at any time. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources, and potentially, damages. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

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

As of March 2, 2023, we had 184 employees and consultants and most of our employees are full-time. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we must add a significant number of additional managerial, operational, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, including additional clinical and FDA or other comparable authority review process for CNTY-101 and our other product 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 CNTY-101 and our other product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. In addition, we expect to incur additional costs in hiring, training, and retaining such additional personnel.

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 and commercialize CNTY-101 and our other product candidates and, accordingly, may not achieve our research, development, and commercialization goals.

The COVID-19 pandemic, or a similar pandemic, epidemic, or outbreak of an infectious disease, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates.

Public health crises, such as pandemics or similar outbreaks, could adversely impact our business. The impact of the COVID-19 pandemic and the efforts to mitigate it, resulted in and will likely continue to result in disruptions to the global economy, as well as businesses and capital markets around the world. We experienced modest delays in our discovery and development activities as a result of the COVID-19 pandemic, primarily due to temporary and partial shutdowns at certain of our CROs and academic institutions that have since resumed operations, and due to governmental responses to the pandemic. We implemented a mandatory vaccination policy for all employees and have taken other precautionary measures, including testing of any employees displaying symptoms of COVID-19. While the vaccines have proven effective in reducing the severity and mortality of COVID-19 including the variants that have evolved to date, the emergence of new variants, which could prove resistant to existing vaccines, could again result in major disruptions to businesses and markets worldwide. The extent to which the COVID-19 pandemic will continue to impact our operations or those of our consultants and collaborators, will depend on future developments, including the global macroeconomic effects of the virus.

Potential disruptions to our preclinical and clinical development efforts related to the COVID-19 pandemic include, but are not limited to, disruptions in our supply chain and our ability to procure the components for each of our product candidates for use in preclinical studies and clinical trials and enrolling patients in clinical trials. The extent to which the outbreak may affect our preclinical studies, clinical trials, business, financial condition, and results of operations will depend on future developments, which are uncertain and cannot be predicted at this time. Additionally, we are unable to predict if a different pandemic could have similar or different impacts on our business, financial condition, or share price. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, business, financial condition, and results of operations.

We have incurred indebtedness, and we may incur additional indebtedness, which could adversely affect our business.

As of December 31, 2022, we had an outstanding balance of \$10.0 million under our Loan and Security Agreement with Hercules Capital, Inc., or the Loan Agreement. Our indebtedness could have important consequences to our stockholders. For example, it:

- increases our vulnerability to adverse general economic and industry conditions;
- limits our flexibility in planning for, or reacting to, changes in our business or the industries in which we operate by restricting our ability to make acquisitions, investments or divestments, or take other corporate actions quickly; and
- limits our ability to obtain additional financing or refinancing in the future for working capital, clinical trials, research and development, or other purposes.

Any of the above-listed factors could materially adversely affect our business, financial condition, results of operations, and cash flows. The Loan Agreement also contains certain financial and other covenants, including limitations on, among other things, additional indebtedness, out licensing, paying dividends in certain circumstances, and making certain acquisitions and investments. Any failure to comply with the terms, covenants and conditions of the Loan Agreement may limit our ability to draw upon additional tranches of term loans and may result in an event of default under such agreement, which could have a material adverse effect on our business, financial condition, and results of operations.

We are subject to various foreign, federal, and state healthcare and privacy laws and regulations, and our failure to comply with these laws and regulations could harm our results of operations and financial condition.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, and customers expose us to broadly applicable foreign, federal and state fraud and abuse, and other healthcare and privacy laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute any products for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons, or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in-kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal liability and amends provisions on the reporting, investigation, enforcement, and penalizing of civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses, and certain healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program (with certain exceptions) to report annually to the CMS information related to payments and other “transfers of value” made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members, and beginning in 2022, applicable manufacturers are required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives;
- the Foreign Corrupt Practices Act, or FCPA, which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-United States officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by the patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug and biologic manufacturers to file reports relating to pricing and marketing information or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives; state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA; state and foreign governments that have enacted or proposed requirements regarding the collection, retention, distribution, use, security, sharing, transfer, storage, and other processing of personally identifiable information and other data relating to individuals (including the EU General Data Protection Regulation 2016/679, or GDPR, and the California Consumer Protection Act, or CCPA), and federal and state consumer protection laws are being applied to enforce regulations related to the online collection, use, and dissemination of data, thus complicating compliance efforts.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations involves substantial costs. It is possible that governmental authorities will conclude that our business practices, including any consulting and advisory board arrangements with

physicians and other healthcare providers, do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, exclusion from United States government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, additional reporting requirements, and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, diminished profits, and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusion from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Healthcare legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates.

The commercial potential for our approved products, if any, could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry. New laws, regulations, or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products, and services could adversely affect our business, operations, and financial condition. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that may affect our ability to profitably sell our products and product candidates, if approved. The United States government, state legislatures, and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs and biologics.

The ACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. There have been significant ongoing administrative, executive, and legislative efforts to modify or eliminate the ACA. For example, the Tax Cuts and Jobs Act, enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Code, commonly referred to as the individual mandate. Other legislative changes have been proposed and adopted since passage of the ACA. The ACA has also been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by the United States Congress, or Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire ACA. An appeal was taken to the U.S. Supreme Court and on June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions.

Further changes to and under the ACA remain possible but it is unknown what form any such changes or any law proposed to replace or revise the ACA would take, and how or whether it may affect our business in the future. We expect that changes to the ACA, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug and biologic prices, and changes stemming from other

healthcare reform measures, especially with regard to healthcare access, financing, or other legislation in individual states, could have a material adverse effect on the healthcare industry.

The Budget Control Act of 2011 has resulted in reductions in spending on certain government programs, including aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year. These reductions have been extended until 2030 although adjustments have been made as a result of the ongoing COVID-19 pandemic. The 2% reduction was suspended through March 31, 2022. Following the suspension, a 1% payment reduction began April 1, 2022, and remained through June 30, 2022. The 2% payment reduction resumed on July 1, 2022.

Any reduction in reimbursement from Medicare, Medicaid, or 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 and maintain profitability of our product and product candidates, if approved.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, CNTY-101 or any future product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would materially adversely affect our business, financial condition, and results of operations.

If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired.

We are required to maintain internal controls over financial reporting. We must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Reports on Form 10-K, as required by Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. This has required us to incur substantial additional professional fees and internal costs to expand our accounting and finance functions and we have expended significant management efforts as compared to prior to our IPO, when we were not required to test our internal controls. If we identify material weaknesses in our internal control over financial reporting in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if our independent registered public accounting firm determines that we have a material weakness or a significant deficiency in our internal control over financial reporting, or we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. As a result, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

We believe that any internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

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. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and may not be detected.

We, or our CMOs or suppliers, may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time-consuming or costly.

We, or our CMOs or suppliers, including FCDI, use biological materials, potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. The operations of our CMOs and suppliers also produce hazardous waste products. Federal, state, and local laws and regulations govern the use, generation, manufacture, storage, handling, and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions or liabilities, which could materially 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 products.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While we currently have no product candidates that have been approved for commercial sale, the future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. For example, we may be sued if CNTY-101 and our other product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability, and a breach of warranties. Claims may be brought against us by clinical trial participants, patients, or others using, administering or selling products that may be approved in the future. 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 or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;

- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing, or promotional restrictions;
- significant negative financial impact;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize CNTY-101 or our other product candidates; and
- a decline in our stock price.

We currently hold product liability coverage in an amount we consider reasonable. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of CNTY-101 or our other product candidates. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of CNTY-101 or our other product candidates. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We may be unable to adequately protect our or our vendors' information systems from cyberattacks or other incidents, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems that we or our third-party providers operate to process, transmit, and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as names, mailing addresses, email addresses, phone numbers, and clinical trial information. Despite our implementation of security measures, our internal computer systems, and those of our CROs, CMOs, information technology suppliers, and other contractors and consultants are vulnerable to damage from computer viruses, cyberattacks, and other unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. Additionally, our security measures or those of our vendors could be breached as a result of employee theft, exfiltration, misuse, malfeasance, or unintentional events. A successful cyberattack or other data security incident could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud, and other forms of cyber fraud, the deployment of harmful malware, ransomware, denial-of-service, social engineering fraud, or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss, and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial, or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or

patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international law (e.g., the GDPR) and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business.

We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for, or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting, and controlling such cyberattacks and any such attacks could result in the losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions, or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects, and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

We also cannot be certain that our existing insurance coverage will cover any claims against us relating to any security incident or breach, will be available in sufficient amounts to cover the potentially significant losses that may result from a security incident or breach, will continue to be available on acceptable terms or at all or that the insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could adversely affect our reputation, business, financial condition, and results of operations.

Failure to comply with current or future federal, state, and foreign laws and regulations and industry standards relating to privacy and data protection laws could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We or our collaborators collect, use, process, store and transfer certain personal and/or confidential information as part of our normal business operations. We are therefore subject to federal, state, and international laws and regulations governing the privacy and security of confidential information and personal data. In the United States, we are subject to numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, governing the collection, use, disclosure, storage, transfer, protection, and disposal of health-related and other the personal and/or confidential information we and/or our collaborators utilize. A failure to comply with these current or future federal, state, and international laws and regulations and industry standards relating to data privacy and security could lead to investigatory or regulatory action, private litigation or class actions that could result in exposure to civil or criminal penalties, monetary or statutory damages, attorney fee awards and/or exposure to adverse publicity that could negatively affect our operating results and business.

Many state legislatures have adopted legislation that regulates how businesses operate online, including measures relating to privacy, data security, and data breaches, and laws in all 50 states require businesses to provide notice to customers whose personally identifiable information has been disclosed as a result of a data breach. Such laws are not consistent, and compliance in the event of a widespread security incident may be costly and could disrupt our operations. By way of example, the CCPA, which went into effect on January 1, 2020, creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Additionally, a new privacy law, the California Privacy Rights Act, or

the CPRA, was approved by California voters in the election of November 3, 2020. The CPRA, which will take effect in most material respects on January 1, 2023, modifies the CCPA significantly, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply.

Foreign data protection laws, including the GDPR, may also apply to health-related and other personal information belonging to individuals who reside outside of the United States. The GDPR went into effect in the European Union in May 2018 and introduced strict requirements for processing the personal data of data subjects residing in the European Economic Area, or EEA. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The GDPR increased our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

The GDPR also regulates cross-border transfers of personal data and requires transferee countries to have protections equivalent to protections available in the EEA. Unless the destination country is an adequate country (as recognized by the European Commission), we will be required to incorporate a GDPR transfer mechanism (such as the European Commission approved standard contractual clauses, or SCCs,) into our agreements with third parties to govern transfers of personal data outside the EEA. The new SCCs may also impact our business as companies based in the EEA may be reluctant to utilize the new clauses to legitimize transfers of personal data to third countries given the burdensome requirements of transfer impact assessments and the substantial obligations that the new SCCs impose upon exporters.

Further, the United Kingdom's exit from the European Union, referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. The United Kingdom has transposed the GDPR into domestic law with a United Kingdom version of the GDPR that took effect in January 2021, or the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but currently still aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Although the UK is regarded as a third country under the EU's GDPR, the European Commission has now issued a decision recognizing the UK as providing adequate protection under the GDPR and, therefore, transfers of personal data originating in the EEA to the UK remain unrestricted. Like the GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. It is not subject to the new forms of SCCs but has issued its own transfer mechanism – the UK international data transfer agreement – which, like the SCCs, requires exporters to carry out a transfer impact assessment. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The UK Government has also now introduced a Data Protection and Digital Information Bill (or the UK Bill) into the UK legislative process with the intention for this bill to reform the UK's data protection regime following Brexit. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EU data protection regime and threaten the UK Adequacy

Decision from the EU Commission. This may lead to additional compliance costs and could increase our overall risk.

Compliance with U.S. federal and state laws and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators to comply with United States and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants, and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless, and/or negligent conduct or disclosure of unauthorized activities to us that violate: (1) the laws and regulations of the FDA and other similar regulatory requirements, including those laws that require the reporting of true, complete, and accurate information to such authorities, (2) manufacturing standards, including cGMP requirements, (3) federal and state data privacy, security, fraud and abuse, and other healthcare laws and regulations in the United States and abroad or (4) laws that require the true, complete, and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of drug or biologic product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement, or similar agreement to resolve allegations of noncompliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks related to our intellectual property

We do not currently own any issued patents relating to our product candidates.

Given the early stage of development of our product candidates, our patent portfolio is similarly at a very early stage. In particular, we do not own any issued patents. If we do not obtain meaningful patent coverage for our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them, and methods of treatment, competitors may be able to erode or negate any competitive

advantage we may have, which would likely harm our business and ability to achieve profitability. To establish our proprietary position, we have filed patent applications in the United States and internationally related to CNTY-101 and have filed provisional patent applications on other aspects of our technology. However, United States provisional patent applications are not eligible to become issued patents unless and until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. With regard to such United States provisional patent applications, if we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage. If we are unable to secure or maintain patent protection with respect to our antibody technology and any proprietary products and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

If any of our license agreements with FCDI are terminated, we could lose our rights to key components enabling our iPSC-derived allogeneic cell therapy platforms.

Our commercial success will depend in part on the maintenance of our license agreements. In September 2018, we entered into an exclusive license with FCDI, pursuant to which we have received an exclusive license to certain patents and know-how related to the differentiation of iPSC cells into immune-effector cells in the field of cancer immunotherapeutics, or the Differentiation License, and a non-exclusive license for the rights to certain patents and know-how related to the reprogramming of human somatic cells to iPSCs in the field of cancer immunotherapeutics, or the Reprogramming License, and together with the Differentiation License, the FCDI Licenses. A critical aspect to manufacturing our product candidates involves the reprogramming of certain cells into iPSCs and the differentiation of iPSCs into immune cells. We utilize technology licensed from FCDI to reprogram cells to become iPSCs and to differentiate the iPSCs to generate different immune cell types including NK cells and T cells. By utilizing this licensed technology, we are currently capable of achieving fully functional iNK cells from iPSCs in approximately 30 days.

The FCDI Licenses impose, and future license agreements may impose, various diligence, milestone payment, royalty, and other obligations on us. If we fail to comply with our obligations under the FCDI Licenses, our other license agreements, or any future license agreements with any party, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to develop products covered by such license.

If, for any reason, the FCDI Licenses or certain of our other license agreements are terminated or we otherwise lose the rights under such agreements, it would adversely affect our business. If we breach any material obligations under the FCDI Licenses or certain of our other license agreements, FCDI or the applicable licensor may have the right to terminate our license, which could result in us being unable to develop, manufacture, or sell our product candidates that incorporate the intellectual property subject to such license. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects, and we may be required to identify and license replacement technology from third parties, which may not be available on reasonable terms or at all.

We may not be successful in obtaining or maintaining necessary intellectual property rights in the future for the development of CNTY-101 and our other product candidates.

We may in the future enter into additional license agreements with third parties for other intellectual property rights or assets to advance our research or allow commercialization of CNTY-101 and our other product candidates, and we cannot provide any assurances that third-party patents do not exist which might be enforced against CNTY-101 and our other product candidates in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive or may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories, 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, which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Licensing of intellectual property is of critical importance to our business and involves complex legal, business, and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues, the resolution of which could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement;
- whether and the extent to which our technology and processes infringe, misappropriate, or otherwise violate intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other intellectual property rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of CNTY-101 and our other product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions, know-how, and other intellectual property 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 prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business.

In addition, certain of our agreements may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, if we choose to sublicense or assign to any third parties our rights under our existing license agreements with respect to any licensed product, we may be required to pay a specified percentage of all revenue to be received in connection with such transaction.

Under one of the FCDI Licenses and certain other in-licenses under which we sublicense certain rights related to our technology, we rely on FCDI and our other sub licensors to comply with their obligations under their upstream license agreements where we may have no relationship with the original licensor of such rights. If our sub licensors fail to comply with their obligations under their upstream license agreements, and the upstream license agreements are consequently terminated, such termination may result in the termination of our sublicenses and loss of such rights.

Our success depends on our ability to obtain, maintain, protect, and enforce our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain, maintain, protect, and enforce our intellectual property and proprietary technologies, including patent protection and trade secret protection for CNTY-101 and our other product candidates, proprietary technologies and their uses as well as our ability to operate without infringing, misappropriating, or otherwise violating the intellectual property or proprietary rights of others. If we are unable to obtain, maintain, protect, or enforce our intellectual property rights or if our intellectual property rights are inadequate for our technology or our product candidates, our competitive position could be harmed, which could have a material adverse impact on our business, results of operations, financial conditions, and prospects. Although we have filed patent applications with respect to CNTY-101 and other aspects of our product technology, our patent portfolio is in an earlier stage of prosecution. We do not own any issued patents related to CNTY-101 and our other product candidates. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents are issued from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents if issued will not be infringed, misappropriated, violated, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our intellectual property and proprietary rights is uncertain. Only limited protection may be available and may not adequately obtain, maintain, protect, and enforce our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly obtain, maintain, protect, and enforce the intellectual property rights relating to CNTY-101 and our other product candidates could have a material adverse effect on our financial condition and results of operations.

Because CNTY-101 is our lead product candidate, and because our other product candidates are based on similar technology, if we are unable to obtain patent protection for CNTY-101, our other product candidates in our pipeline could be significantly impaired, which could materially adversely affect our business, financial conditions, results of operations, and growth prospects.

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, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that claims that may ultimately issue from our patent applications will not be found invalid or unenforceable if challenged. If we are unable to obtain or maintain patent protection with respect to our product candidates, our business, financial condition, results of operations, and prospects could be materially harmed.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting CNTY-101 and our other product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or block our ability to make, use, and sell CNTY-101 and our other product candidates;
- there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop, and market competing products.

The patent prosecution process is also expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, including our collaboration with Bristol-Myers Squibb, we do not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain the patents, directed to technology that we license from third parties or which are filed on products developed under the Collaboration Agreement. We may also require the cooperation of our licensor or Bristol-Myers Squibb in order to enforce the licensed patent rights, and such cooperation may not be provided. 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 patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using, and selling competing products.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, CMOs, consultants, advisors, and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or license

currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether CNTY-101 and our other product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing, misappropriating, or violating manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may not cover CNTY-101 and our other product candidates or may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review, or PGR, and inter parties review, or IPR, or other similar proceedings in the USPTO or foreign patent offices challenging our patent rights. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our predecessors and the patent examiner were unaware during prosecution. There is no assurance that all potentially relevant prior art relating to our patents and patent applications or those of our licensors has been found. There is also no assurance that there is not prior art of which we, our predecessors or licensors are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or those of our licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. An adverse determination in any such submission, proceeding, or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize CNTY-101 and our other product candidates and compete directly with us, without payment to us. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our or our licensors' ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of CNTY-101 and our other product candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates.

The patent protection and patent prosecution for some of our product candidates may be dependent on third parties.

We or our licensors or collaborators may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we, our collaborators or our licensors, whether current or future, fail to establish, maintain, or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

As a licensee of third parties, we rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If any of our licensors or any of our future licensors or future collaborators fail to appropriately prosecute and maintain patent protection for patents covering CNTY-101 and our other product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, and selling competing products.

In addition, even where we have the right to control patent prosecution of patents and patent applications we have acquired or licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our technology acquired or licensed from various third parties may be subject to retained rights. Our predecessors or licensors often retain certain rights under their agreements with us, including the right to use the underlying technology for non-commercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

In addition, the research resulting in certain of our in-licensed patent rights and technology was funded in part by the United States government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The United States government also has the right to take title to these inventions if the applicable licensor fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to United States industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations, and prospects.

If we are limited in our ability to utilize acquired or licensed technologies, or if we lose our rights to critical in-licensed technology, we may be unable to successfully develop, out-license, market, and sell our products, which could prevent or delay new product introductions. Our business strategy depends on the successful development of licensed and acquired technologies into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license, or market and sell CNTY-101 and our other product candidates.

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 our competitive advantage. For example:

- others may be able to develop products that are similar to CNTY-101 and our other product candidates but that are not covered by the claims of the patents that we own or license;
- we or our licensors or predecessors might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;
- we or our licensors or predecessors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating, or otherwise violating our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, it could significantly harm our business, results of operations, and prospects.

Our commercial success depends significantly on our ability to operate without infringing, misappropriating, or otherwise violating the patents and other intellectual property and proprietary rights of third parties. Claims by third parties that we infringe, misappropriate, or violate their intellectual property or proprietary rights may result in liability for damages or prevent or delay our development and commercialization efforts.

Our commercial success depends in part on avoiding infringement, misappropriation, or other violation of the patents, intellectual property, or proprietary rights of third parties. However, our research, development, and commercialization activities may be subject to claims that we infringe, misappropriate, or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or other intellectual property or proprietary rights that could limit our ability to make, use, sell, offer for sale, or import CNTY-101 or our other product candidates that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings, and PGR proceedings before the USPTO and/or foreign patent offices. Numerous third-party United States and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates, including patents and patent applications held by our competitors. There may be third-party patents or patent

applications with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of CNTY-101 and our other product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that CNTY-101 and our other product candidates may be subject to claims of infringement, misappropriation, or other violation of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published we may be unaware of third-party patents that may be infringed by commercialization of CNTY-101 and our other product candidates, and we cannot be certain that we were the first to file a patent application related to CNTY-101 and our other product candidates. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that CNTY-101 and our other product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon, misappropriates, or otherwise violates these patents. Any claims asserted by third parties would be time-consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing CNTY-101 and our other product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Third parties may hold intellectual property or proprietary rights that could prevent CNTY-101 and our other product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin activities relating to CNTY-101 and our other product candidates or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or develop CNTY-101 and our other product 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. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign CNTY-101 and our other product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing CNTY-101 and our other product candidates, which could harm our business, financial condition, and operating results.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings,

there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs, or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

The intellectual property landscape around gene-editing technology is highly dynamic, and third parties may initiate and prevail in legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights.

The field of gene-editing, especially in the area of CRISPR technology, is still in its infancy, and no such products have reached the market. Further, the ownership of intellectual property rights relating to CRISPR technology is not fully established. Accordingly, we may not be able to secure all the necessary rights to practice the technology. Due to the intense research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain for the coming years. There may be significant intellectual property related litigation and proceedings relating to intellectual property and proprietary rights in the future. Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market, and sell any product candidates that we may develop and use our proprietary technologies without infringing, misappropriating, or otherwise violating the intellectual property and proprietary rights of third parties. The biopharmaceutical and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights relating to CRISPR. For example, certain patents are currently subject to Interference Proceedings before the USPTO and Opposition Proceedings before the European Patent Office, or EPO. It is uncertain when and how the USPTO, as well as the EPO, will decide in the various proceedings, and the decisions of the respective patent offices may significantly affect the scope or may deny the validity of the respective patents involved in these proceedings. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to CRISPR technology and any product candidates we may develop. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. If we are unable to prove that these patents are invalid or unenforceable or not infringed and we are not able to obtain or maintain a license on commercially reasonable terms, or at all, such third parties could potentially assert infringement claims against us, which could have a material adverse effect on the conduct of our business. If we are found to infringe, misappropriate, or violate such third-party patents, we and our partners may be required to pay damages, cease commercialization of the infringing technology, including our use of gene-editing technology, or obtain a license from such third parties, which may not be available on commercially reasonable terms or at all.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe, misappropriate, or violate our intellectual property rights or those of our licensors. To prevent infringement, misappropriation, violation, or unauthorized use, we and/or our licensors may be required to file claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or license is not valid, is unenforceable and/or is not infringed. If we or any of our licensors or potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at CNTY-101 and our other product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent

litigation, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our licensors is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business.

In addition, we may in the future choose to challenge the patentability of claims in a third-party's patent by requesting that the USPTO review the patent claims in re-examination, post-grant review, inter parties review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). We have challenged and may in the future choose to challenge third party patents in patent opposition proceedings in the EPO or another foreign patent office. Even if successful, the costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO, or other patent office we may be exposed to litigation by the third party alleging that the relevant patent may be infringed by our product candidates.

Even if resolved in our favor, litigation, or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs, or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

Changes in United States patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect CNTY-101 and our other product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that

may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the United States federal courts, the USPTO, or similar authorities in foreign jurisdictions, 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 we might obtain in the future.

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

We may also be subject to claims that former employees or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. 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 the exclusive right to use, our owned or in-licensed patents. If we or our licensors are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive or of a diminished scope. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, or prospects. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to management and other employees. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other 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. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Patent terms may be inadequate to protect our competitive position on CNTY-101 and our other product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering CNTY-101 and our other product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing, and regulatory review of product candidates, patents protecting CNTY-101 and our other product candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for CNTY-101 and our other product candidates, our business may be materially harmed.

Depending upon the timing, duration, and specifics of FDA marketing approval of CNTY-101 and our other product candidates, one or more of our United States patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or 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. A maximum of one patent may be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, failing to apply prior to expiration of relevant patents or otherwise failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines or failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, we may be reliant on third-party licensors and collaborators in applying for such patent term extensions and we may not be able to obtain their cooperation. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

Although we have licenses to issued patents and pending patent applications in the United States and certain other countries, filing, prosecuting, and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in 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 product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of any patents we ultimately obtain and/or applications we file. We have systems in place to remind us to pay these fees, and we rely on third parties to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. In some cases, we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. However, 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. If such an event were to occur, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business.

If we are unable to protect the confidentiality of our trade secrets, our business, and competitive position would be harmed.

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology, and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants, and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Trade secrets and know-how can be difficult to protect. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Because we currently rely on other third parties to manufacture our product candidates and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology and other trade secrets, in part, by entering into confidentiality agreements, consulting agreements, or other similar agreements with our advisors, employees, consultants, and other third parties prior to beginning research or disclosing proprietary information and other trade secrets. These agreements typically limit the rights of the third parties to use or disclose our confidential information, proprietary information, and other trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occur or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biopharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of CNTY-101 and our other product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biopharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Risks related to our common stock

The trading price of the shares of our common stock has been highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price has been volatile since our initial public offering. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by those factors discussed in this “Risk factors” section and many others, including:

- the commencement, enrollment, or results of our current and future preclinical studies and clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- regulatory approval of our product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory developments in the United States and foreign countries;

- changes in the structure of healthcare payment systems, especially in light of current reforms to the United States healthcare system;
- the success or failure of our efforts to acquire, license, or develop additional product candidates;
- innovations or new products developed by us or our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to our relationship with FCDI, any manufacturers, suppliers, licensors, future collaborators, or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our stock by insiders and stockholders;
- general economic, industry, and market conditions, or other events or factors, many of which are beyond our control;
- additions or departures of key personnel; and
- intellectual property, product liability, or other litigation against us.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition, and results of operations.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

Our executive officers, directors, principal stockholders, and affiliates have the ability to exercise significant control over our company, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

As of December 31, 2022, the existing holdings of our executive officers, directors and affiliates, represented beneficial ownership, in the aggregate, of approximately 24% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and control the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. These stockholders may have interests, with respect to their common stock, that are different from your interests

and the concentration of voting power among these stockholders may have an adverse effect on the price of our common stock. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

We are an emerging growth company and a “smaller reporting company”, and the reduced disclosure requirements applicable to emerging growth companies and “smaller reporting companies” may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or JOBS Act, and may remain an emerging growth company until December 31, 2026. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenues exceed \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. The reduced disclosure and other requirements that we may take advantage of include:

- not being required to have our registered independent public accounting firm attest to management’s assessment of our internal control over financial reporting;
- presenting reduced disclosure about our executive compensation arrangements;
- not being required to hold non-binding advisory votes on executive compensation or golden parachute arrangements; and
- extended transition periods for complying with new or revised accounting standards.

We have taken advantage of reduced reporting burdens in this Annual Report on Form 10-K. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies.

We are also a “smaller reporting company,” meaning that the market value of our stock held by nonaffiliates is less than \$700.0 million and our annual revenue is less than \$100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250.0 million or (ii) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Reports on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

We will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

We became a public company in June 2021. As a public company, and particularly after we are no longer an emerging growth company or smaller reporting company, we have and will continue to incur significant legal, accounting, and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the Securities and Exchange Commission, or the SEC, and The Nasdaq Stock Market LLC, or Nasdaq, impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to comply with these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company or a smaller reporting company with less than \$100 million in annual revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We could be an emerging growth company for up to five years. To achieve compliance with Section 404 of the Sarbanes-Oxley Act within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404 of the Sarbanes-Oxley Act. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market, or our competitors. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

Provisions in our corporate charter documents and under Delaware law could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our second amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent, a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. As our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions provide, among other things, that:

- our board of directors has the exclusive right to expand the size of our board of directors and to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- our board of directors is divided into three classes, Class I, Class II, and Class III, with each class serving staggered three-year terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- our stockholders may not act by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- a special meeting of stockholders may be called only by the chair of our board of directors, our chief executive officer, or a majority of our board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- our second amended and restated certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- our board of directors may alter certain provisions of our amended and restated bylaws without obtaining stockholder approval;
- the approval of the holders of at least two-thirds of the outstanding shares of our capital stock is required to adopt, amend, or repeal our amended and restated bylaws, unless such action is recommended by our board of directors at an annual or special meeting of shareholders;
- the approval of the holders of at least two-thirds of the outstanding shares of our capital stock is required to adopt, amend, or repeal provisions in our second amended and restated certificate of incorporation relating to (i) the amendment of the second amended and restated certificate of incorporation or

amendment of the amended and restated bylaws, (ii) stockholder action, (iii) election and removal of directors, (iv) limitations on liability and (v) exclusive forum for proceedings;

- stockholders must provide advance notice and additional disclosures to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain voting control of our shares; and
- our board of directors is authorized to issue shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, or DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our second amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum 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 second amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or the Exchange Act. Furthermore, our amended and restated certificate of incorporation provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

We could be subject to securities class action litigation.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal executive offices are located in Philadelphia, Pennsylvania, pursuant to a short-term lease. We operate in three laboratory spaces in Philadelphia pursuant to leases that expire in December 2030, October 2031 and February 2034. Additionally, we lease office and laboratory space in Seattle, Washington pursuant to leases expiring in September 2030, respectively and laboratory and office space in Hamilton, Ontario, pursuant to a lease that expires in October 2025. We have finished construction and the operational fit out of a 53,000 square foot cell therapy manufacturing facility on a tract of land in Branchburg, New Jersey pursuant to a lease expiring in February 2037. We believe that our current facilities are adequate to meet our ongoing needs, and that, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings. From time to time, we may become involved in other litigation or legal proceedings relating to claims arising from the ordinary course of business.

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

Our common stock is publicly traded on the Nasdaq Global Market under the symbol "IPSC."

Holder

As of February 28, 2023, we had approximately 115 record holders of our common stock.

Dividends

Our ability to pay cash dividends is currently restricted by the terms of our Loan and Security Agreement with Hercules Capital, Inc., as discussed in Note 9 - "Long term debt" in the notes to our consolidated financial statements.

Use of Proceeds from Initial Public Offering

On June 22, 2021, we completed our IPO. Our registration statement on Form S-1 (File No. 333- 256648) relating to the IPO was declared effective by the SEC on June 17, 2021. We issued an aggregate of 12,132,500 shares of our common stock at a price of \$20.00 per share for aggregate net cash proceeds of \$221.4 million, after deducting approximately \$17.0 million in underwriting discounts and commissions and approximately \$4.0 million in other offering costs. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates.

The sale and issuance of 12,132,500 shares in the IPO closed on June 22, 2021. J.P. Morgan, BofA Securities, SVB Leerink and Piper Sandler acted as joint book-running managers for the IPO.

As of December 31, 2022, the net proceeds from our IPO have been invested in U.S. treasury bills and corporate bonds. There has been no material change in the planned use of proceeds from the IPO from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on June 21, 2021.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Part III, Item 12 of this Annual Report on Form 10-K.

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

Management's discussion and analysis of financial condition and results of operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K and our audited consolidated financial statements and the related notes thereto. This discussion, particularly information with respect to our future results of operations or financial condition, business strategy and plans and objectives of management for future operations, includes forward-looking statements that involve risks and uncertainties as described under the heading "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" in this Annual Report on Form 10-K. You should review the disclosure under the heading "Risk Factors" herein for a discussion of important factors that could cause our actual results to differ materially from those anticipated in these forward-looking statements.

Overview

We are an innovative biotechnology company developing transformative allogeneic cell therapies to create products for the treatment of both solid tumor and hematological malignancies with significant unmet medical need. We have created a comprehensive allogeneic cell therapy platform that includes industry-leading induced pluripotent stem cells, or iPSCs, differentiation know-how to generate immune effector cells from iPSCs, or iPSC-derived cells, clustered regularly interspaced short palindromic repeats, or CRISPR, mediated precision gene editing that allows us to incorporate multiple transgenes and remove target genes intended to optimize cell product performance, sophisticated protein engineering capabilities to develop proprietary next generation chimeric antigen receptors, or CARs, our proprietary Allo-EvasionTM technology intended to prevent rejection of our cell products by the host immune system, and cutting edge manufacturing capabilities intended to minimize product development and supply risk. We believe that these vertically integrated capabilities will allow us to further expand our existing pipeline and develop therapeutics from iPSC-derived natural killer cells, or iNK cells, or iNK, and iPSC-derived T cells, or iT cells, or iT, that may provide enhanced clinical outcomes compared to available therapeutic options. Our vision is to become a premier fully integrated biotechnology company by developing and ultimately commercializing off-the-shelf allogeneic cell therapies that dramatically and positively transform the lives of patients suffering from life-threatening cancers. To achieve our vision, we have assembled a world-class team whose members collectively have decades of experience in cell therapy and drug development, manufacturing, and commercialization.

We were formed in 2018 as Century Therapeutics, Inc., or Prior Century. In 2019, in connection with our investment from Bayer Healthcare LLC, or Bayer, Prior Century contributed substantially all of its operating assets and cash to a newly formed entity, Century Therapeutics, LLC, or the LLC Entity. We refer to this transaction as the 2019 Reorganization. The 2019 Reorganization was accounted for as an asset acquisition under US Generally Accepted Accounting Principles, and as a result we recorded a one-time non-cash charge in the amount of \$225.9 million which represented the fair value of the contributed in-process research and development, or IPR&D, of Prior Century. The IPR&D asset acquired was Prior Century's comprehensive allogeneic cell therapy platform.

Until February 2021, our business was operated through the LLC Entity. In February 2021, in connection with the sale of 24,721,999 shares of our Series C preferred stock, or the Series C Financing, the LLC Entity converted from a Delaware limited liability company to a Delaware C corporation. Upon completion of this conversion, Prior Century, whose only significant asset was its equity investment in LLC, merged with the C corporation, and in connection therewith the C corporation changed its name to "Century Therapeutics, Inc." We refer to these transactions as the 2021 Reorganization.

Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates and preparing to initiate and conduct clinical trials, undertaking preclinical studies and in-licensing intellectual property. All of our programs are currently in the development stage, and we do not have any products approved for sale. Since our inception, we have incurred net losses each year. We had an accumulated deficit of \$519.1 million as of December 31, 2022. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs, the acquisition of in-process research and development and from general and administrative costs associated with our operations. Included in our accumulated deficit, as noted above, is a non-cash expense of \$225.9 million related to the fair value of the in-process research and development of Prior Century.

In August 2022, the FDA notified us that our ELiPSE-1 clinical trial may proceed to assess CNTY-101 in patients with relapsed or refractory CD19 positive B-cell malignancies. The phase 1 trial, ELiPSE-1, is intended to assess the safety, tolerability, pharmacokinetics and preliminary efficacy of CNTY-101 in patients with relapsed or refractory CD19-positive B-cell malignancies. We have initiated our phase 1 trial and in February 2023, we began dosing patients in ELiPSE-1, evaluating CNTY-101.

In June 2021, we completed our initial public offering, or IPO, in which we issued and sold 12,132,500 shares of our common stock, at a public offering price of \$20.00 per share. We received net proceeds of \$221.4 million after deducting underwriting discounts, commissions, and other offering costs of \$21.2 million in the aggregate. To date, we have funded our operations from the issuance and sale of our equity securities and the receipt of payments from Bristol-Myers Squibb, in connection with our collaboration as described below, and have not generated any revenues. Since our inception, we have raised approximately \$591 million in net proceeds from sales of our equity securities. As of December 31, 2022, we had cash and cash equivalents of \$84.3 million and investments of \$283.1 million.

In January 2023, we announced a strategic internal portfolio prioritization through which, among other discovery efforts, CNTY-103, a CAR-iNK product targeting CD133 and a discovery program for hematological malignancies, was de-prioritized, allowing us to further prioritize our CNTY-102 and CNTY-107 product candidates, which we believe have a higher probability of technical success and greater market potential. As a result of the operational restructuring, lab operations in Seattle and Hamilton have been closed and research activities have been consolidated in Philadelphia.

Based on our current business plans and the January 2023 strategic reprioritization, we believe, our cash, cash equivalents and investments as of December 31, 2022, will be sufficient for us to fund our operating expenses and capital expenditures requirements into 2026. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We anticipate that our expenses and operating losses will increase substantially over the foreseeable future. The expected increase in expenses will be driven in large part by our ongoing activities, if and as we:

- continue to advance our iPSC cell therapy platforms;
- progress clinical development of CNTY-101 and continue preclinical development of our other product candidates;
- seek to discover and develop additional product candidates;
- establish and validate our own clinical-scale current good manufacturing practices, or cGMP, facilities;
- seek regulatory approvals for any of our product candidates that successfully complete clinical trials;
- maintain, expand, protect, and enforce our intellectual property portfolio;
- acquire or in-license other product candidates and technologies;

- incur additional costs associated with operating as a public company, which will require us to add operational, financial and management information systems and personnel, including personnel to support our drug development and any future commercialization efforts; and
- increase our employee headcount and related expenses to support these activities.

We are also investing early in building our capabilities in key areas of manufacturing sciences and operations, including development of our iPSC cell therapy platforms, product characterization, and process analytics from the time product candidates are in early research phases. Our investments also include scaled research solutions, scaled infrastructure, and novel technologies intended to improve efficiency, characterization, and scalability of manufacturing.

We anticipate that we will need to raise additional financing in the future to fund our operations, including funding for preclinical studies, clinical trials and the commercialization of any approved product candidates. We intend to use the proceeds from such financings to, among other uses, fund research and development of our product candidates and development programs, including our pre-clinical and clinical development of CNTY-101, CNTY-102, and CNTY-107, as well as CNTY-104 and CNTY-106 in collaboration with Bristol-Myers Squibb. Until such time, if ever, as we can generate significant product revenue, we expect to finance our operations with our existing cash and cash equivalents, investments, any future equity or debt financings, and upfront and milestone and royalties payments, if any, received under future licenses or collaborations. We may not be able to raise additional capital on terms acceptable to us or at all. If we are unable to raise additional capital when desired, our business, results of operations, and financial condition would be adversely affected. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability.

While the COVID-19 pandemic has stabilized within many global regions, it may cyclically continue to adversely affect our business, financial condition and results of operations. The impact of the COVID-19 pandemic and the efforts to mitigate it, resulted in and will likely continue to result in disruptions to the global economy, as well as businesses and capital markets around the world. We experienced modest delays in our discovery and development activities as a result of the COVID-19 pandemic, primarily due to temporary and partial shutdowns at certain of our CROs and academic institutions that have since resumed operations, and due to governmental responses to the pandemic. We implemented a mandatory vaccination policy for all employees and have taken other precautionary measures, including testing of any employees displaying symptoms of COVID-19. While the vaccines have proven effective in reducing the severity and mortality of COVID-19 including the variants that have evolved to date, the emergence of new variants, which could prove resistant to existing vaccines, could again result in major disruptions to businesses and markets worldwide. The extent to which the outbreak may affect our preclinical studies, clinical trials, business, financial condition, and results of operations will depend on future developments, which are uncertain and cannot be predicted at this time.

License and collaboration agreements

Fujifilm Cellular Dynamics, Inc. (FCDI)

On September 18, 2018, we entered into a license agreement, or the Differentiation License, with FCDI. The Differentiation License, as amended, provides us with an exclusive license under certain patents and know-how related to human iPSC consisting of cells that are or are modifications of NK cells, T cells, dendritic cells and macrophages derived from human iPSC. In consideration for the Differentiation License, Prior Century issued 2,980,803 shares of common stock to FCDI, which were exchanged for 2,980,803 shares of common stock in connection with the Reorganization.

Also on September 18, 2018, we entered into the non-exclusive license, or the Reprogramming License, with FCDI. The Reprogramming License, as amended, provides us with a non-exclusive license under certain

patents and know-how related to the reprogramming of human somatic cells to iPSCs and provide us access to iPSC lines for clinical use. Under the Reprogramming License, we are required to make certain developmental and regulatory milestone payments as well as royalty payments upon commercialization in the low single digits. The potential development and regulatory milestone payments to be paid by us to FCDI are approximately \$6 million per licensed product. In connection with the Reprogramming License, we entered into a collaboration agreement, or the FCDI Collaboration Agreement, with FCDI pursuant to which we agreed to fund research and development work at FCDI pursuant to a research plan.

On October 21, 2019, we entered into the FCDI Collaboration Agreement with FCDI, whereby FCDI provides certain services to us to develop and manufacture iPSCs and immune cells derived therefrom. Under the terms of the FCDI Collaboration Agreement, as amended, FCDI will provide services in accordance with the approved research plan and related research budget. The initial research plan covers the period from the date of execution of the FCDI Collaboration Agreement through March 31, 2022. On July 29, 2022 we amended the FCDI Collaboration Agreement to extend the term through September 30, 2025.

On January 7, 2022, we and FCDI entered into a letter agreement, or the Letter Agreement, which amends each of the FCDI agreements as further discussed in Note 11 to our consolidated financial statements. Pursuant to the Letter Agreement, and in consideration for amending the FCDI Agreements, we agreed to pay to FCDI (i) an upfront payment of \$10 million, (ii) a percentage of any milestone payments received by us under the Collaboration Agreement, in respect of achievement of development or regulatory milestones specific to Japan, and (iii) a percentage of all royalties received by us under the Collaboration Agreement in respect of sales of products in Japan.

During the years ended December 31, 2022 and 2021, we made payments of \$5.1 million and \$16.2 million and incurred research and development expenses of \$4.9 million and \$16.7 million, and legal fees of \$0.2 million and \$0.1 million, respectively, related to the FCDI agreements, recorded within general and administrative expenses in its consolidated statements of operations and comprehensive loss. As of December 31, 2022 and 2021, there was \$0 and \$2.4 million in accounts payable related to the FCDI agreements on the consolidated balance sheets.

From inception of the FCDI Collaboration Agreement through December 31, 2022, we incurred \$36.1 million of expenses under the FCDI Collaboration Agreement.

Bristol-Myers Squibb

On January 7, 2022, we entered into the Research, Collaboration and License Agreement, with Bristol-Myers Squibb, or the Collaboration Agreement, to collaborate on the research, development and commercialization of iNK and iT cell programs for hematologic malignancies and solid tumors, or the Collaboration Program, and each product candidate, a Development Candidate. We and Bristol-Myers Squibb will initially collaborate on two Collaboration Programs focused on acute myeloid leukemia, or AML, and multiple myeloma, or MM, and Bristol-Myers Squibb has the option to add up to two additional Collaboration Programs for an additional fee. We are responsible for generating Development Candidates for each Collaboration Program, and Bristol-Myers Squibb has the option to elect to exclusively license the Development Candidates for pre-clinical development, clinical development and commercialization on a worldwide basis, or the License Option. Following Bristol-Myers Squibb's exercise of the License Option, we will be responsible for performing IND-enabling studies, supporting Bristol-Myers Squibb's preparation and submission of an IND, and manufacturing of clinical supplies until completion of a proof of concept clinical trial. Bristol-Myers Squibb will be responsible for all regulatory, clinical, manufacturing (after the proof of concept clinical trial) and commercialization activities for such Development Candidates worldwide. We have the option to co-promote Development Candidates generated from certain specified Collaboration Programs.

Under the terms of the Collaboration Agreement, Bristol-Myers Squibb made a non-refundable, upfront cash payment of \$100 million and will pay an exercise fee upon the exercise of the License Option, or the Licensed Program, and product candidates developed under a Licensed Program, the Licensed Products. For each

Licensed Program, Bristol-Myers Squibb will pay up to \$235 million in milestone payments upon the first achievement of certain development and regulatory milestones and will pay up to \$500 million per Licensed Product in net sales-based milestone payments. Bristol-Myers Squibb will also pay us tiered royalties per Licensed Product as a percentage of net sales in the high-single digits to low-teens, subject to certain adjustments.

In connection with the Collaboration Agreement, Bristol-Myers Squibb purchased 2,160,760 shares of our common stock at a price per share of \$23.14, for an aggregate purchase price of \$50 million. We determined the common stock purchase represented a premium of \$7.82 per share, or \$23.2 million in the aggregate, and the remaining \$26.8 million was recorded as issuance of common stock in stockholders' equity.

iCELL and Distributed Bio

We also have entered into a sublicense agreement with iCELL Inc. and a master services agreement with Distributed Bio, Inc. See Note 12 to our consolidated financial statements.

Components of operating results

Collaboration Revenue

We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products for the foreseeable future. Our revenues to date have been generated through our collaboration, option and license agreement with Bristol-Myers Squibb. We recognize revenue over the expected performance period under this agreement. We expect that our revenue for the next several years will be derived primarily from this agreement and any additional collaborations that we may enter into in the future. To date, we have not received any royalties under any of our existing collaboration agreements.

Operating expenses

Research and development

To date, research and development expenses have related primarily to discovery and development of our iPSC cell therapy platform technology and product candidates and acquired in-process research and development. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are recorded as prepaid expenses until the goods or services are received.

Research and development expenses consist of personnel-related costs, including salaries, and benefits, stock compensation expense, external research and development expenses incurred under arrangements with third parties, laboratory supplies, costs to acquire and license technologies facility and other allocated expenses, including rent, depreciation, and allocated overhead costs, and other research and development expenses.

We deploy our employee and infrastructure resources across multiple research and development programs for developing our iPSC cell therapy platforms, identifying and developing product candidates, and establishing manufacturing capabilities. Due to the number of ongoing projects and our ability to use resources across several projects, the vast majority of our research and development costs are not recorded on a program-specific basis. These include costs for personnel, laboratory, and other indirect facility and operating costs.

Research and development activities account for a significant portion of our operating expenses. We anticipate that our research and development expenses will increase for the foreseeable future as we expand our research and development efforts including expanding the capabilities of our iPSC cell therapy platforms, identifying product candidates, progressing preclinical studies and clinical trials, including for our first clinical

product candidate CNTY-101, seeking regulatory approval of our product candidates, and incurring costs to acquire and license technologies aligned with our goal of translating iPSCs to therapies. A change in the outcome of any of these variables could mean a significant change in the costs and timing associated with the development of our product candidates.

General and administrative

General and administrative expenses consist of personnel-related costs, including salaries, benefits, and non-cash stock-based compensation, for our employees in executive, legal, finance, human resources, information technology, and other administrative functions, legal fees, consulting fees, recruiting costs, and facility costs not otherwise included in research and development expenses. Legal fees include those related to corporate and patent matters.

We anticipate that our general and administrative expenses will increase over the foreseeable future to support our continued research and development activities, operations generally, future business development opportunities, consulting fees, as well as due to the increased costs of operating as a public company.

In-process research and development

As a direct result of the execution of the Collaboration Agreement with Bristol-Myers Squibb, we incurred \$10 million in fees to amend the FCDI agreement to gain access to the territory rights of Japan. See Note 11 to our consolidated financial statements.

Interest expense

Interest expense relates to interest incurred on the Loan Agreement we entered into with Hercules Capital, Inc., or Hercules, in 2020, as well as amortization of the related deferred financing cost. See Note 9 to our consolidated financial statements.

Other income, net

Interest income, net consists of interest earned on our cash, cash equivalents and investment balances.

Income taxes

Until February 25, 2021, we were organized as a limited liability company, which is considered a passthrough entity for federal and state income tax purposes. Subsequent to the conversion of the LLC Entity to a C-Corp on February 25, 2021, we have incurred losses and recorded a full valuation allowance on all of our net deferred tax assets. As of December 31, 2022 and 2021, we recorded \$91 thousand and \$43 thousand, respectively, in provisions for income taxes related to our subsidiary Century Therapeutics Canada ULC in the accompanying consolidated financial statements.

Results of operations

Comparison of the years ended December 31, 2022 and 2021

The following table summarizes our results of operations for the periods presented:

	Year Ended December 31, 2022	Year Ended December 31, 2021 (in thousands)	Change
Collaboration revenue	\$ 5,199	\$ —	\$ 5,199
Operating expenses:			
Research and development	97,173	75,648	21,525
General and administrative	31,857	19,235	12,622
Write off of in-process research and development asset	10,000	—	10,000
Total operating expenses	<u>139,030</u>	<u>94,883</u>	<u>44,147</u>
Loss from operations	<u>(133,831)</u>	<u>(94,883)</u>	<u>(38,948)</u>
Other income (expense):			
Interest expense	(1,430)	(1,275)	(155)
Other income, net	4,420	377	4,043
Total other income (expense)	<u>2,990</u>	<u>(898)</u>	<u>3,888</u>
Loss before provision for income taxes	<u>(130,841)</u>	<u>(95,781)</u>	<u>(35,060)</u>
Provision for income taxes	(91)	(43)	(48)
Net loss	<u>\$ (130,932)</u>	<u>\$ (95,824)</u>	<u>\$ (35,108)</u>

Collaboration revenue

For the year ended December 31, 2022, we recognized revenue of \$5.2 million under our collaboration agreement with Bristol-Myers Squibb. There was no collaboration revenue recognized for the year ended December 31, 2021.

Research and development expenses

The following table summarizes the components of our research and development expenses for the periods presented:

	Year Ended December 31, 2022	Year Ended December 31, 2021 (in thousands)	Change
Personnel and related costs	\$ 42,901	\$ 24,651	\$ 18,250
Facility and other allocated costs	16,759	8,780	7,979
Research and laboratory	28,455	20,747	7,708
Collaborations	5,415	16,669	(11,254)
Consulting	2,697	2,796	(99)
Other	946	2,005	(1,059)
Total research and development expense	<u>\$ 97,173</u>	<u>\$ 75,648</u>	<u>\$ 21,525</u>

Research and development expenses were \$97.2 million and \$75.6 million for the years ended December 31, 2022 and 2021, respectively. The increase of \$21.5 million was primarily due to:

- An increase in personnel-related expenses of \$18.3 million, including an increase of stock-based compensation of \$3.4 million, which was primarily attributable to an increase in headcount to expand our research and development capabilities;
- an increase of \$8 million of facility and other allocated costs, including rent and allocated overhead costs as a result of an expansion of our geographic footprint for office and lab space;
- an increase of \$7.7 million in research and laboratory costs, including laboratory supplies, preclinical and clinical studies;
- a decrease in collaborations of \$11.3 million which is primarily due our collaboration with FCDI. The decline was due to less in process development work in 2022 as the scope of work with FCDI has narrowed down to primarily manufacturing CNTY-101 clinical supply for us, and
- a decrease in other expenses of \$1.0 million

General and administrative expenses

General and administrative expenses were \$31.9 million and \$19.2 million for the years ended December 31, 2022 and 2021, respectively. The increase of \$12.7 million was primarily due to increased personnel-related expenses of \$3.5 million, and an increase of stock-based compensation of \$2.6 million, an increase of \$5.5 million in facilities and information technology, primarily attributable to an increase in headcount to build our infrastructure, increased directors' and officers' insurance expense of \$0.8 million, increased professional fees of \$0.2 million relating to accounting, audit and legal services as well as costs associated with ongoing business activities and operating as a public company.

In-process research and development

In-process research and development expenses was \$10 million for the year ended December 31, 2022. As a direct result of the execution of the Collaboration Agreement with Bristol-Myers Squibb, the Company incurred \$10 million in fees to amend the FCDI agreement to gain access to the territory rights of Japan. See Note 11 to our consolidated financial statements. There was no in-process research and development expenses for the year ended December 31, 2021.

Interest expense

Interest expense was \$1.4 million and \$1.3 million for the years ended December 31, 2022 and 2021, respectively, which related to our Loan Agreement with Hercules.

Other income, net

Other income, net consisted of interest income was \$4.4 million and \$0.4 million for the years ended December 31, 2022 and 2021, respectively, which included interest earned on our cash, cash equivalents, and investment balances. The increase in our interest income was due to higher interest rates earned on average balances of cash, cash equivalents and investments.

Liquidity, capital resources, and capital requirements

Sources of liquidity

To date, we have funded our operations from the issuance and sale of our equity securities, debt financing and collaboration revenues. Since our inception, we have raised approximately \$591 million in net proceeds from the sales of our equity securities. As of December 31, 2022, we had cash, and cash equivalents of \$84.3 million and investments of \$283.1 million. Based on our research and development plans, we believe our existing cash, cash equivalents and investments, will be sufficient to fund our operating expenses and capital expenditures requirements into 2026. Since our inception, we have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of any product candidates for a number of years, if ever. We had an accumulated deficit of \$519.1 million as of December 31, 2022. As further described in Note 3 of our consolidated financial statements, we obtained a cash capital commitment from Bayer totaling \$215 million, from which net proceeds of \$74.8 million were received in June 2019, \$38.1 million were received in November 2020 and \$31.9 million were received in January 2021. The commitment agreement terminated in connection with the Series C Financing, and Bayer has no continuing obligation to invest any additional amounts thereunder. As further described in Note 9 of our consolidated financial statements, we entered into a Loan Agreement with Hercules, pursuant to which net proceeds of \$9.6 million were received by us in September 2020. As further described in Note 10 of our consolidated financial statements, in February 2021, we sold 24,721,999 shares of our Series C preferred stock to certain institutional investors for net proceeds of approximately \$159.6 million. Upon the closing of our IPO, the Series C preferred stock automatically converted into 9,825,513 shares of common stock. On June 22, 2021, we closed our IPO in which we issued and sold 12,132,500 shares of our common stock at a public offering price of \$20.00 per share. We received net proceeds of \$221.2 million after deducting underwriting discounts and commissions and other expenses. As described in Note 11, in January 2022 we entered into a Collaboration Agreement with Bristol-Myers Squibb resulting in an upfront payment of \$100 million. In connection with the Collaboration Agreement, Bristol-Myers Squibb also purchased 2,160,760 shares of our common stock at a price per share of \$23.14, for an aggregate purchase price of \$50 million.

In July 2022, we entered into a Sales Agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, under which we may offer and sell, from time to time in our sole discretion, shares of our common stock, having an aggregate offering price of up to \$150 million through Cowen as sales agent. No sales have been made under the Sales Agreement since its inception.

Future funding requirements

We expect to incur additional losses in the foreseeable future as we conduct and expand our research and development efforts, including conducting preclinical studies and clinical trials, developing new product candidates, establishing internal and external manufacturing capabilities, and funding our operations generally. Based on our current business plans, we believe that our existing cash, cash equivalents, and investments, as of December 31, 2022 will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2026. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. However, we anticipate that we will need to raise additional financing in the future to fund our operations, including the commercialization of any approved product candidates. We are subject to the risks typically related to the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business.

Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, costs, and results of discovery, preclinical development, and clinical trials for our current and future product candidates;

- the number of clinical trials required for regulatory approval of our current and future product candidates;
- the costs, timing, and outcome of regulatory review of any of our current and future product candidates;
- the cost of manufacturing clinical and commercial supplies of our current and future product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing, and prosecuting patent applications, obtaining, maintaining, protecting, and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon, misappropriating, or violating their intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations, licensing, or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire and retain, skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products, and technologies.

Until and unless we can generate substantial product revenue, we expect to finance our cash needs through the proceeds from a combination of equity offerings and debt financings, and potentially through additional license and development agreements or strategic partnerships or collaborations with third parties. Financing may not be available in sufficient amounts or on reasonable terms. In addition, market volatility resulting from the macroeconomic factors such as inflationary pressures, recent liquidity constraints, failures and instability in U.S. and international financial banking systems, political unrest and hostilities, war or other factors could adversely impact our ability to access capital as and when needed. We have no commitments for any additional financing and will likely be required to raise such financing through the sale of additional securities, which, in the case of equity securities, may occur at prices lower than the offering price of our common stock. If we sell equity or equity-linked securities, our current stockholders, may be diluted, and the terms may include liquidation or other preferences that are senior to or otherwise adversely affect the rights of our stockholders. Moreover, if we issue debt, we may need to dedicate a substantial portion of our operating cash flow to paying principal and interest on such debt and we may need to comply with operating restrictions, such as limitations on incurring additional debt, which could impair our ability to acquire, sell or license intellectual property rights which could impede our ability to conduct our business.

Cash flows

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

	Year Ended December 31, 2022	Year ended December 31, 2021
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ 14,052	\$ (89,002)
Investing activities	(13,128)	(298,338)
Financing activities	27,158	417,774
Net increase in cash, cash equivalents, and restricted cash	<u>\$ 28,082</u>	<u>\$ 30,434</u>

Operating activities

Net cash provided by operating activities was \$14.1 million, and net cash used in operating activities was \$89 million for the years ended December 31, 2022 and 2021, respectively. Net cash provided by operating activities during the year ended December 31, 2022 consisted primarily of an increase in deferred revenues of \$118 million, an increase in accrued expenses of \$4 million, an increase in operating lease liability of \$5.3 million, and an increase of non-cash charges of \$20.9 million. The non-cash charges of \$20.9 million consisted primarily of \$10.7 million of stock-based compensation expense, depreciation expense of \$8.4 million, and operating lease expense of \$1.6 million. This increase was partially offset by our net loss of \$130.9 million and net cash outflows from decreases in our accounts payable of \$4.8 million.

Net cash used in operating activities was \$89 million for the year ended December 31, 2021. Net cash used in operating activities during the year ended December 31, 2021 consisted primarily of our net loss of \$95.8 million and net cash outflows from decreases in our accounts payable of \$1.8 million, increases in our prepaid expenses and other assets of \$3.2 million, partially offset by increases in accrued expenses and other liabilities of \$1.5 million, and non-cash charges of \$9.6 million. The non-cash charges of \$9.6 million consisted primarily of \$3.7 million for depreciation expense, stock-based compensation expense of \$4.7 million, and operating lease expense of \$0.8 million.

Investing activities

Cash used in investing activities was \$13.1 million and \$298.3 million for the years ended December 31, 2022 and 2021, respectively. Cash used in investing activities for the year ended December 31, 2022, was \$13 million, which consisted primarily of net purchases of investments of \$254 million, and purchases of property and equipment of \$30.6 million, which was partially offset by net sales of fixed maturity securities of \$271.5 million.

Cash used in investing activities for the year ended December 31, 2021 was \$298.3 million which consisted primarily of net purchases of investments of \$330 million, and purchases of property and equipment of \$45 million partially, which was offset by net sales of fixed maturity securities of \$76.7 million.

Financing activities

Cash provided by financing activities was \$27.2 million and \$417.8 million for the years ended December 31, 2022 and 2021, respectively. Cash provided by financing activities for the year ended December 31, 2022 consisted primarily of proceeds from issuance of shares to Bristol-Myers Squibb for \$26.8 million, and proceeds from issuance of common stock of \$0.3 million.

Cash provided by financing activities for the year ended December 31, 2021 consisted primarily of net proceeds from our initial public offering of \$221.4 million, net proceeds from collection of subscription receivable of \$31.9 million and net proceeds from sale of our Series C preferred shares of \$159.6 million

which upon initial public offering were converted to common stock, and cash of \$2.3 million resulting from Prior Century merging with and into us.

Contractual obligations and commitments

The following table summarizes our significant contractual obligations and commitments as of December 31, 2022:

	Payments Due by Period				
	1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
	(in thousands)				
Operating leases	\$5,184	\$ 17,245	\$ 17,847	\$ 54,049	\$ 94,325
Long-term debt	6,502	3,893	—	—	10,395
Interest on long-term debt ⁽¹⁾	1,136	104	—	—	1,240

(1) Reflects minimum interest payable under the Loan Agreement. Payment herein subject to variable rate debt have been estimated.

Other than as disclosed in the table above, the payment obligations under our license, collaboration, and acquisition agreements as of December 31, 2022 are contingent upon future events such as our achievement of pre-specified development, regulatory, and commercial milestones, or royalties on net product sales. As of December 31, 2022, the timing and likelihood of achieving the milestones and success payments and generating future product sales are uncertain and therefore, any related payments are not included in the table above. We have commitments under operating leases for certain facilities used in our operations. Our leases have initial lease terms ranging from 5 to 16 years.

We also enter into agreements in the normal course of business for sponsored research, preclinical studies, contract manufacturing, and other services and products for operating purposes, which are generally cancelable upon written notice. These obligations and commitments are not included in the table above. See Note 12 to our consolidated financial statements for additional information.

We have entered into a \$10 million Term Loan Agreement with Hercules. Amounts borrowed under the Loan Agreement have an interest-only period of up to 30 months and a maturity date of April 1, 2024. See Note 9 to our consolidated financial statements for additional information.

JOBS Act accounting election

As a company with less than \$1.235 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting requirements that are otherwise generally applicable to public companies. As such, we may take advantage of reduced disclosure and other requirements otherwise generally applicable to public companies, including:

- not being required to have our registered independent public accounting firm attest to management’s assessment of our internal control over financial reporting;
- presenting reduced disclosure about our executive compensation arrangements;
- an exemption from compliance with any requirement that the Public Company Accounting Oversight Board may adopt regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- not being required to hold non-binding advisory votes on executive compensation or golden parachute arrangements; and

- extended transition periods for complying with new or revised accounting standards.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period to enable us to comply with new or revised accounting standards and, therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company.

We will remain an emerging growth company until the earliest of (i) December 31, 2026, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.235 billion, (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700 million as of the last business day of the second fiscal quarter of such year or (iv) the date on which we have issued more than \$1 billion in non-convertible debt securities during the prior three-year period.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates is less than \$700 million and our annual revenue is less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million as of the last business day of the second fiscal quarter of such year. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Critical accounting policies and significant judgments and estimates

Our audited consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the audited consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to our audited consolidated financial statements included elsewhere in this prospectus, we believe that the following accounting policies are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management’s judgments and estimates.

Collaboration Revenue

We may enter into collaboration and licensing agreements with strategic partners for research and development, manufacturing, and commercialization of its product candidates. Payments under these arrangements may include non-refundable, upfront fees; reimbursement of certain costs; customer option fees for additional goods or services; payments upon the achievement of development, regulatory, and commercial milestones; sales of product at certain agreed-upon amounts; and royalties on product sales.

We recognize revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers, or ASC 606. This standard applies to all contracts with customers. When an agreement falls under the scope of other standards, such as ASC Topic 808, Collaborative Arrangements, or ASC 808, we will apply the recognition, measurement, presentation, and disclosure guidance in ASC 606 to the performance obligations in the agreements if those performance obligations are with a customer. Revenue recognized by analogizing to ASC 606 is recorded as collaboration revenue on the statements of operations.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under a collaboration agreement, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations on a relative stand-alone selling price basis; and (v) recognition of revenue when (or as) we satisfy each performance obligation.

As part of the accounting for these arrangements, we must use its judgment to determine the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price. The estimation of the stand-alone selling price may include such estimates as forecasted revenues and costs, development timelines, discount rates, and probabilities of regulatory and commercial success. We also apply significant judgment when evaluating whether contractual obligations represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, assessing the recognition and future reversal of variable consideration and determining and applying appropriate methods of measuring progress for performance obligations satisfied over time. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current deferred revenue. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, non-current.

If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. We evaluate the customer options for material rights or options to acquire additional goods or services for free or at a discount. If the customer options are not determined to represent a material right, no transaction price is allocated to these options and we will account for these options at that time they are exercised. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement.

The obligations under our collaboration agreements may include research and development services to be performed by us for or on behalf of the customer. Amounts allocated to these performance obligations are recognized as we perform these obligations, and revenue is measured based on an inputs method of costs incurred to date of budgeted costs. Under certain circumstances, we may be reimbursed for certain expenses incurred under the research and development services.

At the inception of each arrangement that includes development milestone payments, we evaluate 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 us or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. We evaluate 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, we reevaluate 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 in the statements of operations in the period of adjustment.

Research and development expenses

We record research and development costs in the periods in which they are incurred. We accrue for research and development costs based on the estimated services performed, but not yet invoiced, pursuant to contracts with research institutions or other service providers that conduct and manage preclinical studies and other research services on our behalf and record these costs in accrued and other current liabilities. We make judgments and estimates in determining the accrued liabilities balance at each reporting period. Payments made prior to the receipt of goods or services to be used in research and development are recorded as prepaid expenses until the goods or services are received.

Clinical trial costs are a component of research and development expenses. The Company expenses costs for its clinical trial activities performed by third parties, including clinical research organizations and other service providers, as they are incurred, based upon estimates of the work completed over the life of the individual study in accordance with associated agreements. The Company uses information it receives from internal personnel and outside service providers to estimate the clinical trial costs incurred.

To date, we have not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed may vary from our estimates, resulting in adjustments to expenses in future periods. Changes in these estimates that result in material changes to our accruals could materially affect our results of operations.

Stock-based compensation

We recognize compensation costs related to restricted stock awards, restricted stock shares, and stock options granted to employees and nonemployees based on the estimated fair value of the awards on the date of grant, and we recognize forfeitures as they occur. For restricted stock awards the fair value of our common stock is used to determine the resulting stock-based compensation expense. For stock options we estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option pricing model. The fair value of the stock-based awards is recognized as an expense on a straight-line basis over the requisite service period, which is generally the vesting period.

The Black-Scholes option pricing model requires the use of highly subjective assumptions to determine the fair value of stock-based awards. These assumptions include:

- **Fair Value of Common Stock**—After our IPO in June 2021, the fair value of stock-based awards was determined on the grant date using the closing price of the our common stock. As there was no public market for our common stock before the IPO, the estimated fair value of our common stock was determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. Third-party valuations of our common stock were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation.
- **Expected Term**—The expected term represents the period that the stock-based awards are expected to be outstanding. We use the simplified method to determine the expected term, which is based on the average of the time-to-vesting and the contractual life of the options.

- **Expected Volatility**—Due to lack of trading history for our common stock, the expected volatility is estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a time period equal to the expected term of the stock option grants. The comparable companies are chosen based on their size, stage in the product development cycle, and area of specialty. We will continue to apply this process until sufficient historical information regarding the volatility of our own stock price becomes available.
- **Risk-Free Interest Rate**—The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.
- **Expected Dividend**— We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We do not currently have any material exposure to foreign currency fluctuations and do not engage in any hedging activities as part of our normal course of business.

Interest rate and liquidity risk

We had cash, cash equivalents, and restricted cash of \$86.2 million as of December 31, 2022, which consisted of bank deposits and money market funds. We also had investments of \$283.1 million as of December 31, 2022. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the low risk profile of the instruments in our portfolio, a change in market interest rates would not have a material impact on our financial condition and/or results of operations. Additionally, we had the \$10.0 million borrowing related to the Loan Agreement in September 2020 with a floating interest rate per annum (based on a year of 360 days) equal to (i) the sum of (a) the greater of 6.30% plus (b) the prime rate as reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, or (ii) 9.55%. We are therefore exposed to changes in variable United States interest rates on borrowings under our Loan Agreement. A hypothetical 1% increase in interest rates would not result in a material impact to our business.

In addition, we are subject to liquidity risk. On March 10, 2023, Silicon Valley Bank (“SVB”) was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation (“FDIC”) was appointed as receiver. At the time the FDIC was appointed receiver, we had deposit, sweep and other accounts at SVB, which represented less than 1% of our total cash, cash equivalents, restricted cash and investments. We have established a redundant operating account with a major U.S. banking institution.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and laboratory consumables. We believe that inflation has not had a material effect on our financial statements.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CENTURY THERAPEUTICS, INC.

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Century Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Century Therapeutics, Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, changes in 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 "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at 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 U.S. generally accepted accounting principles.

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/ Ernst & Young LLP

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

Philadelphia, Pennsylvania

March 16, 2023

CENTURY THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	\$ 84,265	\$ 56,445
Short-term investments	231,233	166,434
Escrow deposits, current	220	502
Prepaid expenses and other current assets	4,003	4,773
Total current assets	319,721	228,154
Property and equipment, net	82,785	57,967
Operating lease right-of-use assets	28,945	11,854
Restricted cash	1,979	1,717
Escrow deposits, non-current	—	220
Long-term investments	51,854	135,914
Security deposits	1,260	1,549
Total assets	\$ 486,544	\$ 437,375
Liabilities, convertible preferred stock, and stockholders' equity		
Current liabilities		
Accounts payable	\$ 5,454	\$ 7,596
Accrued expenses and other liabilities	9,841	6,040
Deposit liability	866	980
Long-term debt, current	6,502	1,039
Deferred revenue, current	7,154	—
Total current liabilities	29,817	15,655
Operating lease liability, long term	38,698	14,559
Deposit liability, non-current	718	2,020
Deferred revenue, non-current	110,834	—
Long-term debt, net	3,739	8,903
Total liabilities	183,806	41,137
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, \$ 0.0001 par value, 10,000,000 shares authorized at December 31, 2022 and 2021, and 0 shares issued and outstanding at December 31, 2022 and 2021	—	—
Common stock, \$0.0001 par value, 300,000,000 shares authorized at December 31, 2022 and 2021; 58,473,660 and 55,005,523 shares issued and outstanding at December 31, 2022 and 2021, respectively	6	5
Additional paid-in capital	824,292	785,049
Accumulated deficit	(519,098)	(388,166)
Accumulated other comprehensive loss	(2,462)	(650)
Total stockholders' equity	302,738	396,238
Total liabilities and stockholders' equity	\$ 486,544	\$ 437,375

See accompanying notes to the consolidated financial statements.

CENTURY THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)

	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021
Collaboration revenue	\$ 5,199	\$ —
Operating expenses		
Research and development	97,173	75,648
General and administrative	31,857	19,235
In-process research and development	10,000	—
Total operating expenses	139,030	94,883
Loss from operations	(133,831)	(94,883)
Interest expense	(1,430)	(1,275)
Other income, net	4,420	377
Total other income (expense)	2,990	(898)
Loss before provision for income taxes	(130,841)	(95,781)
Provision for income taxes	(91)	(43)
Net loss	\$ (130,932)	\$ (95,824)
 Net loss per common share		
Basic and Diluted	(2.27)	(2.96)
Weighted average common shares outstanding		
Basic and Diluted	57,755,842	32,392,554
Other comprehensive loss		
Net loss	\$ (130,932)	\$ (95,824)
Unrealized loss on investments	(1,786)	(615)
Foreign currency translation	(26)	(32)
Comprehensive loss	\$ (132,744)	\$ (96,471)

See accompanying notes to the consolidated financial statements.

CENTURY THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share amounts)

	Series A		Series B		Series C		Common Stock	Additional	Subscription	Accumulated	Accumulated	Total
	Convertible	Convertible	Convertible	Convertible	Convertible	Convertible						
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Paid-in	Receivable	Comprehensive	Loss	Equity
Balance, December 31, 2020	35,000,000	\$ 34,922	26,143,790	\$ 144,839	—	\$ —	7,481,861	\$ 217,932	\$ (31,900)	\$ (282,342)	\$ (3)	\$ (106,412)
Receipt of subscription receivable	—	—	—	—	—	—	—	—	31,900	—	—	31,900
Issuance of Series C preferred stock, net	—	—	—	—	24,721,999	159,628	—	—	—	—	—	—
Net assets contributed as result of merger	—	—	—	—	—	—	—	1,061	—	—	—	1,061
Conversion of convertible preferred stock upon initial public offering	(35,000,000)	(34,922)	(26,143,790)	(144,839)	(24,721,999)	(159,628)	34,126,528	339,385	—	—	—	339,388
Issuance of common stock upon initial public offering, net of underwriting discounts and commissions and other issuance cost	—	—	—	—	—	—	12,132,500	221,401	—	—	—	221,402
Issuance of common stock upon the exercise of stock options	—	—	—	—	—	—	199,696	213	—	—	—	213
Vesting of restricted stock	—	—	—	—	—	—	566,033	—	—	—	—	—
Vesting of early exercised stock options	—	—	—	—	—	—	498,905	426	—	—	—	426
Warrants granted for services	—	—	—	—	—	—	—	69	—	—	—	69
Unrealized loss on investments	—	—	—	—	—	—	—	—	—	—	(615)	(615)
Foreign currency translation	—	—	—	—	—	—	—	—	—	—	(32)	(32)
Stock based compensation	—	—	—	—	—	—	—	4,662	—	—	—	4,662
Net loss	—	—	—	—	—	—	—	—	—	(95,824)	—	(95,824)
Balance, December 31, 2021	—	\$ —	—	\$ —	—	\$ —	55,005,523	\$ 785,049	\$ —	\$ (388,166)	\$ (650)	\$ 396,238
Issuance of stock to collaboration partner	—	—	—	—	—	—	2,160,760	26,812	—	—	—	26,813
Issuance of common stock upon the exercise of stock options	—	—	—	—	—	—	342,833	345	—	—	—	345
Vesting of restricted stock	—	—	—	—	—	—	488,758	—	—	—	—	—
Vesting of early exercised stock options	—	—	—	—	—	—	475,786	1,417	—	—	—	1,417
Stock based compensation	—	—	—	—	—	—	—	10,669	—	—	—	10,669
Unrealized loss on investments	—	—	—	—	—	—	—	—	—	—	—	—
Foreign currency translation	—	—	—	—	—	—	—	—	—	—	(1,786)	(1,786)
Net loss	—	—	—	—	—	—	—	—	—	(130,932)	(26)	(130,932)
Balance, December 31, 2022	—	\$ —	—	\$ —	—	\$ —	58,473,660	\$ 824,292	\$ —	\$ (519,098)	\$ (2,462)	\$ 302,738

See accompanying notes to the consolidated financial statements.

CENTURY THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31, 2022	Year Ended December 31, 2021
Cash flows from operating activities		
Net loss	\$ (130,932)	\$ (95,824)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	8,440	3,748
Amortization of deferred financing cost	299	306
Non-cash operating lease expense	1,631	834
Stock based compensation	10,669	4,662
Warrants issued for services	—	69
Change in operating assets and liabilities:		
Escrow deposit	502	784
Prepaid expenses and other assets	1,028	(3,182)
Operating lease liability	5,258	(41)
Deferred revenue	117,988	—
Accounts payable	(4,788)	(1,848)
Accrued expenses and other liabilities	3,957	1,490
Net cash provided by (used in) operating activities	14,052	(89,002)
Cash flows from investing activities		
Acquisition of property and equipment	(30,604)	(44,970)
Acquisition of fixed maturity securities, available for sale	(254,000)	(330,034)
Sale of fixed maturity securities, available for sale	271,476	76,666
Net cash used in investing activities	(13,128)	(298,338)
Cash flows from financing activities		
Proceeds from initial public offering, net of underwriting discounts and commissions	—	221,402
Proceeds from issuance of common stock	345	213
Proceeds from early exercises of common stock options	—	2,305
Proceeds from subscription receivable	—	31,900
Proceeds from issuance of Series C preferred stock, net of issuance costs	—	159,628
Cash contributed as a result of merger	—	2,326
Proceeds from issuance of shares to collaboration partner	26,813	—
Net cash provided by financing activities	27,158	417,774
Net increase in cash, cash equivalents, and restricted cash	28,082	30,434
Cash, cash equivalents and restricted cash, beginning of period	58,162	27,728
Cash, cash equivalents and restricted cash, end of period	\$ 86,244	\$ 58,162
Supplemental disclosure of cash and non-cash operating activities:		
Cash paid for interest	\$ 1,097	\$ 969
Cash paid for income tax	\$ —	\$ 14
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of convertible preferred stock upon initial public offering	—	339,388
Purchase of property and equipment, accrued and unpaid	\$ 2,654	\$ 1,360

See accompanying notes to the consolidated financial statements.

CENTURY THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1—Organization and description of the business

The Company (as defined below) is an innovative biotechnology company developing transformative allogeneic cell therapies to create products for the treatment of both solid tumor and hematological malignancies with significant unmet medical need. Century Therapeutics, Inc. (“Prior Century”), was incorporated in the state of Delaware on March 5, 2018. Since inception, Prior Century has devoted substantially all of its time and efforts to performing research and development activities and raising capital.

On June 5, 2019, Century Therapeutics, LLC (the “Company”) was formed by Prior Century and entered into an LLC Agreement (“Agreement”). On June 21, 2019, Prior Century, through the execution of a commitment agreement and other transaction documents (altogether the “Commitment Agreement”) with Bayer Health, LLC (“Bayer”), financed the creation of the Company and amended the Agreement to account for the provisions in the Commitment Agreement that outlined the rights, obligations, and capital contributions of both Bayer and Prior Century in accordance with the newly executed and amended Agreement and related Commitment Agreement (the “Transaction”). The Transaction resulted in Prior Century contributing substantially all of its assets, liabilities, and operations in exchange for a retained 72% equity interest in the Company. Subsequent to June 21, 2019, Prior Century had no significant operations and accounted for its interest in the Company under the equity method of accounting.

In June 2020, the Company formed Century Therapeutics Canada ULC (“Century Canada”), a wholly owned subsidiary, to acquire the assets of Empirica Therapeutics, Inc. (“Empirica”).

On February 25, 2021, the Company converted from a Delaware limited liability company to a Delaware corporation, and changed its name to “CenturyTx, Inc.” Upon completion of this conversion, Prior Century merged with and into CenturyTx, Inc., with CenturyTx, Inc. as the surviving entity and CenturyTx, Inc. changed its name to “Century Therapeutics, Inc.” In connection with this merger, the holders of equity interests in Prior Century received equivalent equity interests in Century Therapeutics, Inc.

On June 22, 2021, the Company completed its initial public offering (“IPO”) of 10,550,000 shares of Common Stock. On June 22, 2021, the Company sold an additional 1,582,500 shares of Common Stock from the exercise of the overallotment option granted to the underwriters in the IPO. The public offering price of the shares sold in the IPO was \$20.00 per share. The Company raised a total of \$242,650 in gross proceeds from the offering, or \$221,402 in net proceeds after deducting underwriting discounts and commissions of \$16,985 and other offering costs of approximately \$4,263. Upon the closing of the offering, all shares of the Company’s redeemable convertible preferred stock automatically converted into 34,126,528 shares of common stock.

Principles of Consolidation

The consolidated financial statements include the consolidated financial position and consolidated results of operations of the Company and Century Canada. All intercompany balances and transactions have been eliminated in consolidation.

Liquidity

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has limited operating history and its prospects are subject to risks, expenses, and uncertainties frequently encountered by companies in the biotechnology and pharmaceutical industries. These risks include, but are not limited to, the uncertainty of availability of additional financing and the uncertainty of achieving future profitability.

Since inception, the Company has incurred net losses and negative cash flows from operations. During the year ended December 31, 2022, the Company incurred a net loss of \$130,932 and generated \$14,052 of cash from operations. Cash and cash equivalents and short and long-term investments were \$367,352 at December 31, 2022. Management expects to incur additional losses in the future to fund its operations and conduct product research and preclinical and clinical development and recognizes the need to raise additional capital to fully implement its business plan. The Company believes it has adequate cash and financial resources to operate for at least the next 12 months from the date of issuance of these consolidated financial statements.

Note 2—Summary of significant accounting policies and basis of presentation

Basis of presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“US GAAP”), which contemplate the continued existence of the Company. Since commencing principal activities, the Company has been engaged primarily in research and development activities and raising capital.

Merger and capital restructuring

Upon the conversion of Century Therapeutics, LLC to a corporation and the merger of the newly converted corporation with Prior Century, the existing capital structure of Century Therapeutics, LLC was restructured with no consideration transferred. In accordance with ASC 505-10-S99-4, such a restructuring requires retroactive effect within the balance sheets presented. As such, the Company retroactively adjusted its consolidated balance sheets to cancel the existing LLC units and give effect to their conversion into capital stock of the Company as if those effects happened as of January 1, 2020. See Note 10 for further information on the Company’s capital restructuring.

Reverse Stock Split

In June 2021, the Company’s Board of Directors approved an amendment to the Company’s amended and restated certificate of incorporation to effect a 2.5161-for-1 reverse stock split of the Company’s common stock, which was effected on June 11, 2021. Stockholders entitled to fractional shares as a result of the reverse stock split received a cash payment in lieu of receiving fractional shares. The par value of the common stock was not adjusted as a result of the reverse stock split. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the appropriate securities agreements. Shares of common stock reserved for issuance upon the conversion of the convertible preferred stock were proportionately reduced and the respective conversion prices were proportionately increased. All common share and per share data have been retrospectively revised to reflect the reverse stock split.

Segment information

Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions on how to allocate resources and assess performance. The Company views its operations and manages the business as one operating segment.

Use of estimates

The preparation of consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of

expenses during the reporting period. Estimates and assumptions are primarily made in relation to the valuations supporting stock compensation, the estimation of the incremental borrowing rate for operating leases and standalone selling prices of performance obligations in collaboration agreements. If actual results differ from the Company's estimates, or to the extent these estimates are adjusted in future periods, the Company's results of operations could either benefit from, or be adversely affected by, any such change in estimate.

Concentration of credit risk and other risks and uncertainties

Financial instruments, which potentially subject the Company to significant concentrations of credit risk, consist of cash, cash equivalents, U.S. Treasury bills and bonds, as well as corporate bonds. Cash and cash equivalents, as well as short and long-term investments include a checking account and asset management accounts held by a limited number of financial institutions. At times, such deposits may be in excess of insured limits. As of December 31, 2022 and 2021, the Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, rapid technological change, uncertainty of market acceptance of its products, competition from substitute products and larger companies, protection of proprietary technology, strategic relationships, and dependence on key individuals.

Products developed by the Company require clearances from the U.S. Food and Drug Administration or other international regulatory agencies prior to commercial sales. There can be no assurance the Company's future products will receive the necessary clearances. If the Company was denied clearance, clearance was delayed, or if the Company was unable to maintain clearance, it could have a material adverse impact on the Company.

Fair value of financial instruments

The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

Level 1 Inputs that reflect unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date;

Level 2 Inputs other than quoted prices that are observable for the asset or liability either directly or indirectly, including inputs in markets that are not considered to be active;

Level 3 Inputs are unobservable in which there is little or no market data available, which require the reporting entity to develop its own assumptions that are unobservable.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

Cash and cash equivalents

Management considers all highly liquid investments with an insignificant interest rate risk and original maturities of three months or less to be cash equivalents.

Restricted cash

As of December 31, 2022 and 2021, the Company had \$1,979 and \$1,717 in cash on deposit to secure certain lease commitments. Restricted cash is recorded separately in the Company's consolidated balance sheets.

The following provides a reconciliation of the Company's cash, cash equivalents, and restricted cash as reported in the consolidated balance sheets to the amounts reported in the consolidated statements of cash flows:

	December 31, 2022	December 31, 2021
Cash and cash equivalents	\$ 84,265	\$ 56,445
Restricted cash	1,979	1,717
Cash, cash equivalents, and restricted cash.	<u>\$ 86,244</u>	<u>\$ 58,162</u>

Investments

The Company invests in fixed maturity securities including U.S. Treasury bills and bonds as well as corporate bonds. The investments are classified as available-for-sale and reported at fair value. Unrealized gains or losses are determined by comparing the fair market value of the securities with their cost or amortized cost. Realized gains and losses on investments are recorded on the trade date and are included in the statement of operations. Unrealized gains and losses on investments are recorded in other comprehensive income (loss) on the consolidated statements of operations and comprehensive loss. The cost of securities sold is based on the specified identification method. Investment income is recognized as earned and discounts or premiums arising from the purchase of debt securities are recognized in investment income using the interest method over the remaining term of the security. Securities with an original maturity date greater than three months that mature within one year of the balance sheet date are classified as short-term, while investments with a maturity date greater than one year are classified as long-term.

Property and equipment, net

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which is generally five years. Leasehold improvements are amortized over the shorter of the asset's useful life or the remaining term of the lease. Construction in progress includes direct cost related to the construction of leasehold improvements and is stated at original cost. Such costs are not depreciated until the asset is completed and placed into service. Once the asset is placed into service, these capitalized costs will be allocated to leasehold improvements and will be depreciated over the shorter of the asset's useful life or the remaining term of the lease. Computer software and equipment includes implementation costs for cloud-based software and network equipment.

Expenditures for major additions and improvements are capitalized, while minor replacements, maintenance, and repairs are charged to expense as incurred. When property is retired or otherwise disposed of, the costs and accumulated depreciation are removed from the respective accounts, with any resulting gain or loss recognized concurrently.

Research and development expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, stock compensation,

materials, supplies, rent, depreciation on and maintenance of research equipment with alternative future use, and the cost of services provided by outside contractors. All costs associated with research and development are expensed as incurred.

Clinical trial costs are a component of research and development expenses. The Company expenses costs for its clinical trial activities performed by third parties, including clinical research organizations and other service providers, as they are incurred, based upon estimates of the work completed over the life of the individual study in accordance with associated agreements. The Company uses information it receives from internal personnel and outside service providers to estimate the clinical trial costs incurred.

Stock-based compensation

Employees, consultants and members of the board of directors of the Company have received stock options and restricted stock of the Company. The Company recognizes the cost of the stock-based compensation incurred as its employees and board members vest in the awards. The Company accounts for stock-based compensation arrangements in accordance with provisions of Accounting Standards Codification (“ASC”) 718, Compensation—Stock Compensation. ASC 718 requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options. ASC 718 requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The Company uses the Black-Scholes option-pricing model (“Black Scholes”) to determine the fair value of options granted. The Company’s stock-based awards are subject to service-based vesting conditions and performance-based vesting conditions. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. For performance-based awards, the Company reassesses at each reporting date whether achievement of the performance condition is probable and accrues compensation expense if and when achievement of the performance condition is probable.

Black-Scholes requires inputs based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of a public market for the Company’s common stock prior to its IPO and lack of company-specific historical and implied volatility data, the Company based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with expected term assumption. The Company uses the simplified method to calculate the expected term for options granted to employees and board members whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the options due to its lack of sufficient historical data. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock. Forfeitures are recognized as they occur.

Warrants

The Company has issued warrants that have been recognized as equity, and the fair value is recorded into additional paid-in capital in the accompanying consolidated balance sheets. Warrants are accounted for in accordance with applicable accounting guidance provided in ASC Topic 815, Derivatives and Hedging—Contracts in Entity’s Own Equity, as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. The Company’s warrants issued are in connection with its long-term debt and in connection with services provided by consultants, and are equity classified on the accompanying consolidated balance sheets. Equity classified warrants are accounted for at fair value on the issuance date, using Black Scholes, with no changes in fair value recognized after the issuance date.

Foreign currency translation

The reporting currency of the Company is the U.S. dollar. The functional currency of Century Canada is the Canadian dollar. Assets and liabilities of Century Canada are translated into U.S. dollars based on exchange rates at the end of each reporting period. Expenses are translated at average exchange rates during the reporting period. Gains and losses arising from the translation of assets and liabilities are included as a component of accumulated other comprehensive loss or income on the company's consolidated balance sheets. Gains and losses resulting from foreign currency transactions are reflected within the Company's consolidated statements of operations and comprehensive loss. The Company has not utilized any foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

Intercompany payables and receivables are considered to be long-term in nature and any change in balance due to foreign currency fluctuation is included as a component of the Company's consolidated comprehensive loss and accumulated other comprehensive loss within the Company's consolidated balance sheets.

Basic and diluted net loss per common shares

Basic net loss per common share is computed by dividing net loss applicable to common shareholders by the weighted-average number of common shares outstanding during the period. The Company computes diluted net loss per common share by dividing the net loss applicable to common shareholders by the sum of the weighted- average number of common shares outstanding during the period plus the potential dilutive effects of its warrants, restricted stock and stock options to purchase common shares, but such items are excluded if their effect is anti-dilutive. Because the impact of these items are anti-dilutive during periods of net loss, there were no differences between the Company's basic and diluted net loss per common share for the years ended December 31, 2022 and 2021.

Early exercised options

The Company allowed certain of its employees and its consultants to exercise options granted under the 2018 Plan (Note 16) prior to vesting and prior to its IPO. The shares related to early exercised stock options are subject to the Company's repurchase right upon termination of employment or services at the lesser of the original purchase price or fair market value at the time of repurchase. In order to vest, the holders are required to provide continued service to the Company. The early exercise by an employee or consultant of a stock option is not considered to be a substantive exercise for accounting purposes, and therefore, the payment received by the employer for the exercise price is recognized as a liability. For accounting purposes, unvested early exercised shares are not considered issued and outstanding and therefore not reflected as issued and outstanding in the accompanying consolidated balance sheets or the consolidated statements of changes in convertible preferred stock and stockholders' equity (deficit) until the awards vest. The deposits received are initially recorded in deposit liability. The liabilities are reclassified to common stock and additional paid-in-capital as the repurchase right lapses. At December 31, 2022 and 2021, there were \$1,584 and \$3,000, respectively, recorded in deposit liability related to shares held by employees and nonemployees that were subject to repurchase.

All shares that were early exercised by the executives of the Company are considered legally issued, however, for accounting purposes, only vested shares are considered issued. Below is a reconciliation of shares issued and outstanding:

	<u>December 31, 2022</u>	<u>December 31, 2021</u>
Total shares legally outstanding	59,137,491	56,633,898
Less: unvested early exercised shares	(470,800)	(946,586)
Less: unvested restricted stock (Note 17)	(193,031)	(681,789)
Total shares issued and outstanding	<u>58,473,660</u>	<u>55,005,523</u>

Income Taxes

The Company accounts for income taxes under 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 included in the financial statements. Under this method, the Company determines deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. The Company recognizes deferred tax assets to the extent that the Company believes that these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If the Company determines that it would be able to realize its deferred tax assets in the future in excess of their net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes. The Company records uncertain tax positions in accordance with ASC 740 on the basis of a two-step process in which (1) the Company determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations and comprehensive loss. As of December 31, 2022 and 2021, no accrued interest or penalties are included on the related tax liability line in the consolidated balance sheet.

Collaboration revenue

The Company may enter into collaboration and licensing agreements with strategic partners for research and development, manufacturing, and commercialization of its product candidates. Payments under these arrangements may include non-refundable, upfront fees; reimbursement of certain costs; customer option fees for additional goods or services; payments upon the achievement of development, regulatory, and commercial milestones; sales of product at certain agreed-upon amounts; and royalties on product sales.

The Company recognizes revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers, or ASC 606. This standard applies to all contracts with customers. When an agreement falls under the scope of other standards, such as ASC Topic 808, Collaborative Arrangements, or ASC 808, the Company will apply the recognition, measurement, presentation, and disclosure guidance in ASC 606 to the performance obligations in the agreements if those performance obligations are with a customer. Revenue recognized by analogizing to ASC 606 is recorded as collaboration revenue on the statements of operations.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under a collaboration agreement, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations on a relative stand-alone selling price basis; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

As part of the accounting for these arrangements, the Company must use its judgment to determine the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price. The estimation of the stand-alone selling price may include such estimates as forecasted revenues and costs, development timelines, discount rates, and probabilities of regulatory and commercial success. The Company also applies significant judgment when evaluating whether contractual obligations

represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, assessing the recognition and future reversal of variable consideration and determining and applying appropriate methods of measuring progress for performance obligations satisfied over time. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current deferred revenue. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, non-current.

If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. The Company evaluates the customer options for material rights or options to acquire additional goods or services for free or at a discount. If the customer options are not determined to represent a material right, no transaction price is allocated to these options and the Company will account for these options at that time they are exercised. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement.

The obligations under the Company's collaboration agreements may include research and development services to be performed by the Company for or on behalf of the customer. Amounts allocated to these performance obligations are recognized as the Company performs these obligations, and revenue is measured based on an inputs method of costs incurred to date of budgeted costs. Under certain circumstances, the Company may be reimbursed for certain expenses incurred under the research and development services.

At the inception of each arrangement that includes development milestone payments, 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 in the statements of operations in the period of adjustment.

Recent accounting pronouncements

Recently issued accounting pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses: Measurement of Credit Losses of Financial Instruments (ASC 326). The guidance is effective for the Company beginning January 1, 2023 and it changes how entities account for credit losses on the financial assets and other instruments that are not measured at fair value through net income, including available-for-sale debt securities. The Company is currently evaluating the impact of the new standard on its consolidated financial statements.

Note 3—Initial capitalization

On June 21, 2019, Prior Century and Bayer entered into a Commitment Agreement to initially capitalize the Company. The Commitment Agreement called for capital contributions from Prior Century and Bayer as follows:

Century Capital Contributions

In exchange for issuing 67,226,891 common units to Prior Century, the Company acquired substantially all of Prior Century's assets, assumed all of its liabilities and assumed the operations of Prior Century. The Company evaluated the acquisition under the guidance within ASU 2017-01, "Clarifying the Definition of a Business" and concluded that the group of assets acquired did not meet the definition of a business, and, as such, the acquisition was accounted for under the asset acquisition model. The definition of a business was not met because substantially all the fair value of the assets acquired were concentrated in an in-process research and development ("IPR&D") asset. In an asset acquisition, the total transaction cost is allocated between the acquired identified tangible and intangible assets based on relative fair value.

Total transaction costs for the assets acquired were \$252,107, which was the fair value of the equity interests issued to Prior Century, with no additional capitalizable transaction costs. Equity issuance costs related to Prior Century were \$407, which were recorded as a reduction to members' equity. The relative fair value allocation was as follows:

	<u>As of June 21, 2019</u>
Cash and cash equivalents	\$ 25,163
IPR&D	225,946
Property and equipment	1,034
Other current assets	578
Other non-current assets	669
Current liabilities	(1,283)
Total	\$ 252,107

Under the asset acquisition model, an entity that acquires IPR&D assets follows the guidance in ASC 730, which requires that both tangible and intangible identifiable research and development assets with no alternative future use be initially allocated a portion of the consideration transferred and then charged to expense at the acquisition date. The IPR&D asset acquired was Prior Century's comprehensive allogenic cell therapy platform. As the IPR&D asset has no alternative future use to the Company, the Company charged \$225,946 to expense within its consolidated statements of operations in 2019.

Bayer Capital Contributions

In accordance with the Commitment Agreement, Bayer agreed to provide an aggregate cash capital contribution of \$215,000. The Bayer cash commitment was split into capital contributions of \$145,000 ("Tranche 1") and \$70,000 ("Tranche 2"). Tranche 2 was eliminated in connection with the Series C preferred financing. See Note 10.

Bayer Rights

In connection with the Commitment Agreement, Bayer was granted approval and veto rights over certain decisions related to the operations of the Company through its manager representation on the Company's Board of Managers. Prior Century held similar rights.

Tranche 1 was funded in exchange for 26,143,790 common units, with \$75,000 paid at closing and the remaining \$70,000 due upon the Company meeting certain development milestones or in 3 years.

During 2019, the Company received \$74,839 from Tranche 1, net of equity issuance costs of \$161. The Company accounted for the \$70,000 as a subscription receivable, which was recorded as contra-equity within its consolidated statements of changes in convertible preferred stock and stockholders' equity (deficit). On June 18, 2020, the Company, Prior Century and Bayer executed an amendment to the Commitment Agreement to modify the terms for the Company to receive the remaining Tranche 1 subscription receivable of \$70,000. In November 2020, the Company received proceeds of \$38,100 of the Tranche 1 subscription

receivable. The remaining \$31,900 was received in January 2021. The Commitment Agreement terminated in connection with the Series C Preferred financing, and Bayer has no obligation to invest any additional amounts. In addition, upon the closing of the Company's IPO and the conversion of the Company's preferred stock into common stock in connection therewith, all approval, veto and representation rights held by Bayer and other holders of preferred stock terminated.

Bayer Option Agreement

As a condition of the Tranche 1 closing, Bayer and Prior Century were required to enter into an Option Agreement, pursuant to which Bayer was provided the right of first refusal to acquire certain products researched and developed by the Company. Bayer's right of first refusal is exercisable with respect to up to four products. Subject to certain exceptions, Bayer may only exercise these option rights in a non-sequential and alternating manner, and such rights are subject to additional limitations.

Note 4—Asset purchase by Century Therapeutics Canada ULC

On June 9, 2020, Century Canada and the Company entered into an agreement with Empirica, a company focused on the development of adoptive immunotherapies against aggressive and treatment-resistant forms of cancers, including glioblastoma and brain metastasis. Under the terms of the Empirica Agreement, the Company acquired an IPR&D asset. Cash of \$4,519 was paid at closing and transaction expenses totaled \$203. The Company also deposited \$1,506 in escrow (the "Escrow Deposit"). Release of the Escrow Deposit is subject to the terms of a promissory note, which provides for the funds to be released in equal annual installments over a three-year period related to continuing services by certain Empirica shareholders who are employed by the Company. In July 2021, the first annual installment of \$523 was released from escrow. In June 2022, the second annual installment of \$517 was release from escrow. As of December 31, 2022 and 2021, accrued compensation expense on the promissory note was \$220 and \$261, which is presented within escrow deposits on the consolidated balance sheets.

Note 5—Financial instruments and fair value measurements

The following table sets forth the Company's assets that were measured at fair value as of December 31, 2022, by level within the fair value hierarchy:

	Level 1	Level 2	Level 3	Total
Cash equivalents	\$ 77,736	—	—	\$ 77,736
U.S. Treasury	86,475	—	—	86,475
Corporate bonds	—	196,603	—	196,603
Total	<u>\$ 164,211</u>	<u>\$ 196,603</u>	<u>\$ —</u>	<u>\$ 360,814</u>

The following table sets forth the Company's assets that were measured at fair value as of December 31, 2021, by level within the fair value hierarchy:

	Level 1	Level 2	Level 3	Total
Cash equivalents	\$ 52,882	—	—	\$ 52,882
U.S. Treasury	79,752	—	—	79,752
Corporate bonds	—	222,596	—	222,596
Total	<u>\$ 132,634</u>	<u>\$ 222,596</u>	<u>\$ —</u>	<u>\$ 355,230</u>

There were no transfers between levels during the years ended December 31, 2022 and 2021. The Company uses the services of its investment manager, which uses widely accepted models for assumptions in valuing securities with inputs from major third-party data providers.

The Company classifies all of its investments in fixed maturity debt securities as available-for-sale and, accordingly, are carried at estimated fair value.

The amortized cost, gross unrealized gains and losses, and fair value of investments in fixed maturity securities are as follows as of December 31, 2022:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury	\$ 87,798	\$ —	\$ (1,323)	\$ 86,475
Corporate bonds	197,668	2	(1,067)	196,603
Total	<u>\$ 285,466</u>	<u>\$ 2</u>	<u>\$ (2,390)</u>	<u>\$ 283,078</u>

The amortized cost, gross unrealized gains and losses, and fair value of investments in fixed maturity securities are as follows as of December 31, 2021:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury	\$ 80,052	\$ —	\$ (300)	\$ 79,752
Corporate bonds	222,898	—	(302)	222,596
Total	<u>\$ 302,950</u>	<u>\$ —</u>	<u>\$ (602)</u>	<u>\$ 302,348</u>

The following table provides the maturities of the Company's fixed maturity available-for-sale securities:

	December 31, 2022	December 31, 2021
Less than one year	\$ 231,224	\$ 166,434
One to five years	51,854	135,914
	<u>\$ 283,078</u>	<u>\$ 302,348</u>

The Company has evaluated the unrealized losses on the fixed maturity securities and determined that they are not attributable to credit risk factors. For fixed maturity securities, losses in fair value are viewed as temporary if the fixed maturity security can be held to maturity and it is reasonable to assume that the issuer will be able to service the debt, both as to principal and interest.

Note 6—Prepaid expenses and other current assets

The following is a summary of prepaid expenses and other current assets:

	December 31, 2022	December 31, 2021
Research and development	\$ 110	\$ 210
Insurance	1,454	1,606
Software licenses	1,417	2,033
Reimbursement receivable	780	250
Warranties	242	424
Other	—	250
Total prepaid expenses and other current assets	<u>\$ 4,003</u>	<u>\$ 4,773</u>

Note 7—Property and equipment, net

The following is a summary of property and equipment, net:

	December 31, 2022	December 31, 2021
Lab equipment	\$ 28,811	\$ 18,114
Leasehold improvements	48,951	8,365
Construction in progress	13,998	32,836
Computer software and equipment	3,132	2,623
Furniture and fixtures	1,548	1,358
Total	<u>96,440</u>	<u>63,296</u>
Less: Accumulated depreciation	<u>(13,655)</u>	<u>(5,329)</u>
Property and equipment, net	<u>\$ 82,785</u>	<u>\$ 57,967</u>

Depreciation expense was \$8,440 and \$3,748 for the years ended December 31, 2022 and 2021, respectively.

Note 8—Accrued expenses and other liabilities

The following is a summary of accrued expenses:

	December 31, 2022	December 31, 2021
Payroll and bonuses	\$ 7,062	\$ 4,445
Interest	117	82
Accrued clinical trial related costs	314	—
Professional and legal fees	1,637	796
Operating lease liability, current	475	615
Other	236	102
Total accrued expenses and other liabilities	<u>\$ 9,841</u>	<u>\$ 6,040</u>

Note 9—Long-term debt

The following is a summary of the Company's indebtedness:

	December 31, 2022	December 31, 2021
Principal	\$ 10,000	\$ 10,000
Plus: End of term fee	395	395
Less: Debt discount attributable to warrants, net of accretion	(8)	(25)
Less: Unamortized deferred financing cost and end of term fee, net of accretion	<u>(146)</u>	<u>(428)</u>
Long-term debt, net	<u>\$ 10,241</u>	<u>\$ 9,942</u>

On September 14, 2020, the Company entered into a \$10,000 Term Loan Agreement (as amended, the “Loan Agreement”) with Hercules Capital, Inc. (“Hercules”). Pursuant to the terms of the Loan Agreement, the Company borrowed \$10,000 (the “Tranche 1 Advance”) from the lenders at closing. Beginning January 1, 2021 and upon the achievement of certain development milestones and continuing through September 30, 2021 the Company may borrow an additional \$10,000 (the “Tranche 2 Advance”). The remaining \$10,000 tranche (“Tranche 3 Advance”) is subject to Hercules’ investment committee’s sole discretion.

The Loan Agreement has a four-year term and an interest-only period of up to 30 months. The Company was in compliance with all provisions of the Loan Agreement as of December 31, 2022. Amounts borrowed under the Loan Agreement accrue interest at a floating rate per annum (based on a year of 360 days) equal to (i) the sum of (a) the greater of 6.30% plus (b) the prime rate as reported in *The Wall Street Journal* on the last business day of the month that immediately precedes the month in which the interest will accrue or (ii) 9.55%. The interest rate as of December 31, 2022 and 2021 was 13.8% and 9.55%, respectively.

The Company incurred \$410 in deferred financing costs. The Company is also required to pay the lenders an end of term fee of 3.95% of loan proceeds upon repayment or prepayment of any loans made under the Loan Agreement. The end of term fee is being recognized as interest expense and accreted over the term of the Loan Agreement using the effective interest method. The Company is also required to pay Hercules a prepayment charge equal to 2.00% of the loan amounts prepaid during the interest-only period and 1.00% thereafter on any loans made under the Loan Agreement.

The Company granted Hercules a lien on substantially all of the Company’s assets, excluding intellectual property.

The Company issued to Hercules warrants to purchase up to an aggregate of 16,112 shares of common stock. The warrants are exercisable for a period of ten years from the date of the issuance of each warrant at a per share exercise price equal to \$13.96, subject to certain adjustments as specified in the warrants. The fair value of the warrants at issuance was \$46. The Company accounted for the warrants as equity, and the fair value is recorded in additional paid-in capital. The warrant value is also recorded as a debt discount and classified as a contra- liability on the consolidated balance sheet and amortized to interest expense. If the Company borrows on the remaining two tranche advances outlined above, the Company will be required to issue warrants to Hercules equal to 2.25% of the aggregate amount funded.

Interest expense of the Loan Agreement is as follows:

	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021
Interest expense	\$ 1,105	\$ 969
Amortization of debt issuance costs, including end of term fee accretion . . .	299	306
	<u>\$ 1,404</u>	<u>\$ 1,275</u>

Included in accrued expenses in the accompanying consolidated balance sheets as of December 31, 2022 and 2021 was \$117 and \$82 of accrued interest, respectively.

Future principal payments due (including the end of term fee) under the Loan Agreement are as follows (in thousands):

	Principal Payments
2023.	\$ 6,502
2024.	3,893
Total future payments.	<u>\$ 10,395</u>

Note 10—Stockholders' Equity

On February 25, 2021, the Company converted from a Delaware limited liability company to a Delaware corporation, and changed its name to CenturyTx, Inc. Upon completion of this conversion, Prior Century merged with and into CenturyTx, Inc., with CenturyTx, Inc. as the surviving entity and changed its name to "Century Therapeutics, Inc." In connection with this merger, the holders of equity interests, including Series A Preferred Stock, common stock, restricted common stock and stock options in Prior Century received equivalent equity interests in Century Therapeutics, Inc. Bayer's common units in the Company were converted into Series B Preferred Stock.

Upon the execution of the preceding conversion on February 25, 2021, the Company entered into a stock purchase agreement with existing and new investors whereby the Company issued and sold 24,721,999 shares of Series C Preferred Stock with a par value of \$0.0001, to investors at a price of \$6.472 per shares for gross proceeds of \$160,000.

Pursuant to its Amended Articles of Incorporation filed on February 25, 2021, the Company was authorized to issue 125,236,190 shares of \$0.0001 par value common stock and 85,865,789 shares of \$0.0001 par value Preferred Stock. Of the Preferred Stock, 35,000,000 shares are designated as Series A Preferred Stock, 26,143,790 are designated as Series B Preferred Stock and 24,721,999 are designated as Series C Preferred Stock.

On June 22, 2021 when the Company closed its IPO, all outstanding shares of the Series A Preferred Stock, Series B Preferred Stock, and Series C Preferred Stock were converted into an aggregate of 34,126,528 shares of Common Stock automatically and without any action on the part of the holder thereof. The per share conversion price of each of the Series A Preferred Stock, Series B Preferred Stock, and Series C Preferred Stock was equal to \$1.00, \$5.55 and \$6.472, respectively. The Company is authorized to issue up to 300,000,000 shares of common stock with a par value of \$0.0001 per share and 10,000,000 shares of undesignated preferred stock with a par value of \$0.0001 per share.

Note 11 – Bristol-Myers Squibb Collaboration

On January 7, 2022, the Company entered into the Collaboration Agreement with Bristol-Myers Squibb to collaborate on the research, development and commercialization of iNK and iT cell programs for hematologic malignancies and solid tumors ("Collaboration Program," and each product candidate a "Development Candidate"). The Collaboration Agreement is within the scope of ASC 808, Collaborative Arrangements as both parties are active participants in the arrangement and are exposed to significant risks and rewards. While this arrangement is in the scope of ASC 808, the Company analogizes to ASC 606 for the accounting for the Collaboration Agreement, including for the delivery of goods and services (i.e., units of account). Revenue recognized by analogizing to ASC 606 is recorded as collaboration revenue in the statements of operations.

Pursuant to the Collaboration Agreement, the Company and Bristol-Myers Squibb will initially collaborate on two Collaboration Programs focused on acute myeloid leukemia ("AML") and multiple myeloma ("MM"), and Bristol-Myers Squibb has the option to add up to two additional Collaboration Programs for an additional fee. The Company is responsible for generating Development Candidates for each Collaboration Program, and Bristol-Myers Squibb has the option to elect to exclusively license the Development Candidates for pre-clinical development, clinical development and commercialization on a worldwide basis ("License Option"). Following Bristol-Myers Squibb's exercise of the License Option, the Company will be responsible for performing IND-enabling studies, supporting Bristol-Myers Squibb's preparation and submission of an IND, and manufacturing of clinical supplies until completion of a proof of concept clinical trial. Bristol-Myers Squibb will be responsible for all regulatory, clinical, manufacturing (after the proof of concept clinical trial) and commercialization activities for such Development Candidates worldwide. The Company has the option to co-promote Development Candidates generated from certain specified Collaboration Programs.

Under the terms of the Collaboration Agreement, Bristol-Myers Squibb made a non-refundable, upfront cash payment of \$100,000 and will pay an exercise fee upon the exercise of the License Option (“Licensed Program” and product candidates developed under a Licensed Program, “Licensed Products”). For each Licensed Program, Bristol-Myers Squibb will pay up to \$235,000 in milestone payments upon the first achievement of certain development and regulatory milestones and will pay up to \$500,000 per Licensed Product in net sales-based milestone payments. Bristol-Myers Squibb will also pay the Company tiered royalties per Licensed Product as a percentage of net sales in the high-single digits to low-teens, subject to reduction for biosimilar competition, compulsory licensing and certain third party license costs. If Century exercises its co-promote option, such royalty percentage will be increased to low-teens to high-teens in respect of the sales of the co-promoted Licensed Products in the United States. The royalty term shall terminate on a Licensed Product-by-Licensed Product and country-by-country basis on the latest of (i) the twelve (12) year anniversary of the first commercial sale of such Licensed Product in such country, (ii) the expiration of any regulatory exclusivity period that covers such Licensed Product in such country, and (iii) the expiration of the last-to-expire licensed patent of the Company or a jointly owned patent that covers such the Licensed Product in such country. After expiration of the applicable royalty term for a Licensed Product in a country, all licenses granted by the Company to Bristol-Myers Squibb for such Licensed Product in such country will be fully paid-up, royalty- free, perpetual and irrevocable.

In connection with the Collaboration Agreement, Bristol-Myers Squibb purchased 2,160,760 shares of the Company’s common stock at a price per share of \$23.14, for an aggregate purchase price of \$50,000. In determining the fair value of the common stock issued to Bristol-Myers Squibb, the Company considered the closing price of the common stock on the date of the transaction and included a lack of marketability discount because the shares are subject to certain restrictions. The Company determined the common stock purchase represented a premium of \$7.82 per share, or \$23,200 in the aggregate (“Equity Premium”), and the remaining \$26,800 was recorded as issuance of common stock in stockholders’ equity.

The Company identified the following commitments under the arrangement: (i) research and development services (“R&D Services”) under each of the two initial Collaboration Programs and (ii) Bristol-Myers Squibb’s License Option to elect to exclusively license the Development Candidates for each of the two initial Collaboration Programs. The Company determined that these four commitments represent distinct performance obligations for purposes of recognizing revenue and will recognize revenue as the Company fulfills each performance obligation.

The Company determined that the upfront payment and Equity Premium constitute the transaction price at the inception of the Collaboration Agreement. The future potential development and regulatory milestone payments were fully constrained at contract inception as the risk of significant revenue reversal related to these amounts has not yet been resolved. The achievement of the future potential milestones is not within the Company’s control and is subject to certain research and development success and therefore carries significant uncertainty. The Company will reevaluate the likelihood of achieving these milestones at the end of each reporting period and adjust the transaction price in the period the risk is resolved. In addition, the Company will recognize any consideration related to sales-based milestones and royalties when the subsequent sales occur.

At December 31, 2022, the total transaction price of \$123,200 is allocated to the performance obligations based on their estimated standalone selling price. The stand-alone selling price of the research and development services was estimated using the expected cost-plus margin approach, and the stand-alone selling price of the License Options was based on a discounted cash flow approach and considered several factors including, but not limited to, discount rate, development timeline, regulatory risks, estimated market demand, and future revenue potential using an adjusted market approach. The allocated transaction price is recognized as revenue in one of two ways:

- Research and development services: The Company recognizes the portion of the transaction price allocated to each of the research and development performance obligations as the research and development services are provided, using an inputs method, in proportion to costs incurred to date for

each research development target as compared to total costs incurred and expected to be incurred in the future to satisfy the underlying obligation related to each research and development target. The transfer of control occurs over this period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation.

- License option rights: The transaction price allocated to the license options rights, which are considered material rights to license and commercialize the underlying research and development target, are deferred until the period that Bristol-Myers Squibb elects to exercise or elects to not exercise its option or when the option to exercise expires.

The following table summarizes the allocation of the total transaction price to the identified performance obligations under the arrangement, and the amount of the transaction price unsatisfied as of December 31, 2022:

Performance obligations:	Transaction price	Cumulative collaboration revenue recognized	Deferred collaboration revenue
Option rights	\$ 109,164	\$ -	\$ 109,164
Research and development services	14,023	(5,199)	8,824
Total	123,187	(5,199)	117,988
Less current portion of deferred revenue .	-	-	(7,154)
Total long-term deferred revenue	<u>\$ 123,187</u>	<u>\$ (5,199)</u>	<u>\$ 110,834</u>

As a direct result of the execution of the Collaboration Agreement, the Company incurred \$10,000 in fees to amend the FCDI agreement to gain access to the territory rights of Japan. This is recorded as in-process research and development expenses in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2022.

Note 12—Commitments and contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when future expenditures are probable and such expenditures can be reasonably estimated.

Distributed Bio Master Service Agreement

On July 24, 2019, the Company entered into a Master Service Agreement with Distributed Bio, Inc (“DBio”), whereby DBio will screen for protein binders that bind to specific therapeutic targets. The Company pays for such services according to a payment schedule, and if the Company brings the protein binders into the clinic for further development, DBio will receive milestone payments of up to \$16,100 in total for each product as the products move through the clinical development and regulatory approval processes. No milestone payments were due since the inception of the agreement.

The Company had \$110 within accounts payable as of December 31, 2022 and \$36 within accrued expenses and other liabilities as of December 31, 2021, in its consolidated balance sheets related to the Master Service Agreement.

iCELL Inc. Sublicense Agreement

In March 2020, the Company entered into a Sublicense Agreement with iCELL Inc (“iCELL”) whereby iCELL granted the Company a license of certain patents and technology. The Company will pay iCELL royalties in the low single digits on net sales of the licensed product. In addition to the earned royalties, the Company will pay sales milestones, not to exceed \$70,000, for the sales of the licensed product. iCELL is also eligible to

receive payments of up to \$4,250 in development and regulatory approval milestone payments. No milestones or royalties were due in 2022 or 2021.

University of Toronto and McMaster University

In connection with the Empirica asset acquisition in June 2020 (Note 4), the Company acquired a license agreement by and among the Governing Council of the University of Toronto, or the Council, the McMaster University, or, together with the Council, the Toronto Universities, and Empirica (the Empirica License). Under the Empirica License, the Company received an exclusive, non-transferable, sublicensable, worldwide license to certain patents and antibody sequences and related intellectual property rights and know-how.

Pursuant to the Empirica License, the Company is required to make aggregate milestone payments of \$18,000 to the Toronto Universities upon the achievement of regulatory approval for certain products developed pursuant to the Empirica License. The Company is also required to make royalty payments to the Toronto Universities in an amount equal to a low single-digit percentage of annual net sales of any product commercialized utilizing technology licensed. The Company is also required to pay the Toronto Institutions 50% of all non-royalty payments from sublicenses up to certain maximum amounts and 50% of royalty payments from sublicenses up to a maximum low single-digit percentage.

The Empirica License expires upon the expiration of the last-to-expire valid claim covering the antibody and antibody-derived technology licensed under the agreement, which, if issued, is expected to expire in 2037. The Toronto Universities may immediately terminate the agreement upon certain insolvency events and the Company may terminate the agreement for convenience upon 30 days' written notice.

Note 13—Leases

The Company has commitments under operating leases for certain facilities used in its operations. The Company maintains security deposits on certain leases in the amounts of \$1,260 and \$1,549 within security deposits in its consolidated balance sheets at December 31, 2022 and 2021, respectively. The Company's leases have initial lease terms ranging from 5 to 16 years. Certain lease agreements contain provisions for future rent increases. Variable lease costs generally include common area maintenance and real estate taxes.

The following table reflects the components of lease expense:

	<u>For the Year Ended December 31, 2022</u>	<u>For the Year Ended December 31, 2021</u>
Operating lease expense:		
Fixed lease cost	\$ 4,803	\$ 2,256
Variable lease cost	1,261	709
Short term lease expense	2,600	2,628
Total operating lease expense	<u>\$ 8,664</u>	<u>\$ 5,593</u>

The following table reflects supplemental balance sheet information related to leases:

	Location in Balance Sheet	<u>As of December 31, 2022</u>	<u>As of December 31, 2021</u>
Operating lease right-of-use asset, net	Operating lease right-of-use assets	\$ 28,945	\$ 11,854
Operating lease liability, current	Accrued expenses and other liabilities	\$ 475	\$ 615
Operating lease liability, long-term	Operating lease liability, long-term	38,698	14,559
Total operating lease liability		<u>\$ 39,173</u>	<u>\$ 15,174</u>

The following table reflects supplement lease term and discount rate information related to leases:

	<u>As of December 31, 2022</u>	<u>As of December 31, 2021</u>
Weighted-average remaining lease terms - operating leases	9.4 years	8.0 years
Weighted-average discount rate - operating leases	9.0 %	9.0 %

The following table reflects supplemental cash flow information related to leases as of the periods indicated:

	<u>For the Year Ended December 31, 2022</u>	<u>For the Year Ended December 31, 2021</u>
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	\$ 5,258	\$ (41)
Right-of-use assets obtained in exchange for lease obligations:	\$ 19,599	\$ 3,295

The following table reflects future minimum lease payments under noncancelable leases as of December 31, 2022:

	<u>Operating Leases</u>
2023	\$ 5,184
2024	8,540
2025	8,705
2026	8,833
2027	9,014
Thereafter	54,049
Total lease payments	94,325
Less: Imputed interest	(48,703)
Less: Tenant incentive receivable	(6,449)
Total	<u>\$ 39,173</u>

Note 14—Income taxes

Until February 25, 2021, the Company was organized as a limited liability company, which is considered a passthrough entity for federal and state income tax purposes. As such, any taxable income or loss realized by the Company for the period ended February 25, 2021 was allocated to the members in accordance with their respective membership interest and reported on their individual tax returns.

Income (loss) before provision for income taxes consisted of the following (in thousands):

	Year Ended December 31,	
	2022	2021
Domestic	\$ (131,314)	\$ (96,002)
Foreign	473	178
Loss before provision for income taxes	<u>\$ (130,841)</u>	<u>\$ (95,824)</u>

The components of the provision for income taxes is as follows:

	Year Ended December 31,	
	2022	2021
Current expense:		
Federal	\$ -	\$ -
State	-	-
Foreign	86	43
Total current expense:	<u>86</u>	<u>43</u>
Deferred expense:		
Federal	-	-
State	-	-
Foreign	5	-
Total deferred expense:	<u>5</u>	<u>-</u>
Total income tax expense	<u>\$ 91</u>	<u>\$ 43</u>

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

	Year Ended December 31,	
	2022	2021
Income at US statutory rate	21.0%	21.0%
State taxes, net of federal benefit	11.0%	10.5%
Permanent differences	0.6%	0.5%
Tax credits	1.9%	4.3%
Non-taxable income	0.0%	(0.5)%
Valuation allowance	(33.8)%	(32.2)%
Change in entity tax status	0.0%	(0.7)%
Other	(0.7)%	(3.0)%
	<u>0.0%</u>	<u>(0.1)%</u>

The net deferred income tax asset balance related to the following:

	Year Ended December 31,	
	2022	2021
Deferred Tax Assets		
Net operating loss carryforwards	\$ 35,187	\$ 28,537
Lease liability	12,236	5,127
Accrued expenses & other	605	1,530
Research & Development (R&D) tax credits	5,351	4,211
Capitalized R&D expenses	28,693	-
Stock based compensation	3,391	729
Amortization	4,304	1,500
Total deferred tax assets	<u>89,767</u>	<u>41,634</u>
Valuation allowance	<u>(78,469)</u>	<u>(34,262)</u>
Net deferred tax assets	<u>11,298</u>	<u>7,372</u>
Deferred tax liability		
Depreciation	(2,264)	(3,366)
Right-of-use asset	<u>(9,039)</u>	<u>(4,006)</u>
Total deferred tax liabilities	<u>(11,303)</u>	<u>(7,372)</u>
Net deferred tax liability	<u>\$ (5)</u>	<u>\$ -</u>

As of December 31, 2022, the Company had an indefinite-lived federal net operating loss carryforward of \$104,300. As of December 31, 2022, the Company has state and local NOL carryforwards of \$109,700 and \$152,800, respectively. The state net operating loss carryforwards will begin to expire in 2039. As of December 31, 2022, the Company also has federal tax credits of \$5,351, which begin to expire in 2039.

Future realization of the tax benefits of existing temporary differences and net operating loss carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2022 and 2021, the Company performed an evaluation to determine whether a valuation allowance was needed. The Company considered all available evidence, both positive and negative, which included the results of operations for the current and preceding years. The Company determined that it was not possible to reasonably quantify future taxable income and determined that it is more likely than not that all of the deferred tax assets will not be realized. Accordingly, the Company maintained a full valuation allowance against its net US DTAs as of December 31, 2022 and 2021.

Under Internal Revenue Code Section 382, if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. The Company has not completed a study to assess whether an “ownership change” has occurred or whether there have been multiple ownership changes since it became a “loss corporation” as defined in Section 382. Future changes in the Company’s stock ownership, which may be outside of our control, may trigger an “ownership change.” In addition, future equity offerings or acquisitions that have equity as a component of the purchase price could result in an “ownership change.” If an “ownership change” has occurred or does occur in the future, utilization of the NOL carryforwards or other tax attributes may be limited, which could potentially result in increased future tax liability to the Company.

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss and research and development tax credit carryforwards. Under the applicable accounting standards, management has considered the Company’s history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets. Accordingly, a full valuation allowance was maintained against the Company’s net US DTAs as of December 31, 2022 and 2021. A change in the Company’s valuation allowance was recorded in 2022, in the amount of \$44,207 due primarily to the generation of additional net operating losses and the associated gross deferred tax assets.

The Tax Cuts and Jobs Act (TCJA) resulted in significant changes to the treatment of research and developmental (R&D) expenditures under Section 174. For tax years beginning after December 31, 2021, taxpayers are required to capitalize and amortize all R&D expenditures that are paid or incurred in connection with their trade or business. Specifically, costs for U.S.-based R&D activities must be amortized over five years and costs for foreign R&D activities must be amortized over 15 years—both using a midyear convention. During the year ended December 31, 2022, the Company capitalized \$101,600 of R&D expenses.

The calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations for both federal taxes and the many states in which we operate or do business in. ASC 740 states that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.

The Company records uncertain tax positions as liabilities in accordance with ASC 740 and adjust these liabilities when its judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from its current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. As of December 31, 2022 and 2021, the Company has not recorded any uncertain tax positions in its financial statements.

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations. As of December 31, 2022 and 2021, no accrued interest or penalties are recorded.

The Company files tax returns 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's tax years are still open under statute from December 31, 2019, to the present. The resolution of tax matters is not expected to have a material effect on the Company's consolidated financial statements.

Note 15—Basic and diluted net loss per common share

Basic and diluted net loss per common share is calculated as follows:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Numerator		
Net loss.....	\$ (130,932)	\$ (95,824)
Denominator		
Weighted-average common shares for basic and diluted net loss per share	57,755,842	32,392,554
Basic and diluted net loss per common share	<u>\$ (2.27)</u>	<u>\$ (2.96)</u>

The Company's potentially dilutive securities, which include the convertible preferred stock, restricted stock, warrants, early exercised stock options and stock options to purchase shares of the Company's common stock, have been excluded from the computation of dilutive net loss per share as the effect would be antidilutive. Therefore, the weighted- average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same. The Company excluded the following potential shares of common stock presented based on amounts outstanding at each stated period end, from

the computation of diluted net loss per share for the years ended December 31, 2022 and 2021 because including them would have had an anti-dilutive effect.

	Year Ended December 31, 2022	Year Ended December 31, 2021
Stock options to purchase common stock	7,489,678	5,678,604
Early exercised stock options subject to future vesting	470,800	946,586
Restricted stock award subject to future vesting	193,031	681,789
Warrants	32,009	32,009
Total	<u>8,185,518</u>	<u>7,338,988</u>

Note 16—Defined contribution plan

The Company has a 401(k) Employee Savings Plan (“401(k) Plan”) that is available to all employees of the Company. The Company has elected a Safe-Harbor provision for the 401(k) Plan in which participants are always fully vested in their employer contributions. The Company matches 100% of the first 3% of participating employee contributions and 50% of the next 2% of participating employee contributions. Contributions are made in cash. Contributions were approximately \$862 and \$536 for the year ended December 31, 2022 and 2021 respectively. Such contribution expense has been recognized in the consolidated statement of operations for each period.

Note 17—Stock-based compensation

As part of the merger discussed in Note 2 above, the Company adopted from Prior Century, the 2018 Stock Option and Grant Plan (the “Plan”). The Plan provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the Board of Directors, and consultants of the Company under terms and provisions established by the Board of Directors. Under the terms of the Plan, options may be granted at an exercise price not less than fair market value.

The Company’s stock-based awards are subject to service-based vesting conditions and performance-based vesting conditions. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Stock awards granted typically vest over a four-year period but may be granted with different vesting terms. For performance-based awards, the Company reassesses at each reporting date whether achievement of the performance condition is probable and accrues compensation expense if and when achievement of the performance condition is probable. On June 17, 2021, this plan was replaced by the Century Therapeutics, Inc. 2021 Equity Incentive Plan (the “2021 Incentive Plan”) and future issuances of incentive awards will be governed by that plan.

Upon adoption of the 2021 Incentive Plan, the Company was authorized to issue 5,481,735 shares of Common Stock under the 2021 Incentive Plan (which represents 5,640,711 shares of Common Stock initially available for grant under the 2021 Incentive Plan less 158,976 shares of Common Stock reserved for issuance upon the exercise of previously granted stock options that remain outstanding under the 2018 Incentive Plan).

The 2021 Employee Stock Purchase Plan (the “2021 ESPP”) was approved by the board of directors on May 27, 2021. A total of 564,071 shares of common stock were initially reserved for issuance under this plan. No shares are issued or outstanding under the 2021 ESPP.

On January 1, 2022, the Company was authorized to issue an additional 2,750,276 shares of Common Stock under the 2021 Incentive Plan and an additional 550,055 shares of Common Stock under the 2021 ESPP pursuant to “evergreen” provisions contained in each of the 2021 Incentive Plan and 2021 ESPP.

The Company recognizes the costs of the stock-based payments as the employees vest in the awards. For the year ended December 31, 2022, the Company recognized \$10,669 of stock-based compensation expense of which \$4,954 was general and administrative expense and \$5,715 was research and development expenses recorded within the consolidated statement of operations and comprehensive loss. For the year ended December 31, 2021, the Company recognized \$4,662 of stock-based compensation expense of which \$2,357 was general and administrative expense and \$2,305 was research and development expenses recorded within the consolidated statement of operations and comprehensive loss.

Stock Options

The following table summarizes stock option activity for the year ended December 31, 2022:

	Shares	Weighted Average		Aggregate Intrinsic Value (in thousands)
		Exercise Price	Remaining Contractual Term (years)	
Outstanding January 1, 2022	5,678,604	\$ 5.36	8.35	\$ 11,595
Granted	2,550,270	12.40	—	—
Exercised	(342,833)	1.01	—	—
Forfeited	(301,877)	8.43	—	—
Cancelled	(94,486)	—	—	—
Outstanding, December 31, 2022	7,489,678	\$ 7.77	7.84	\$ 8,991
Exercisable at December 31, 2022	3,212,790	\$ 4.35	7.34	\$ 6,864

The weighted average grant date fair value of awards for options granted during the period ended December 31, 2022 was \$8.13. As of December 31, 2022, there was \$26,645 of total unrecognized compensation expense related to unvested stock options with time-based vesting terms, which is expected to be recognized over a weighted average period of 2.61 years. The aggregate intrinsic value of options vested and exercisable as of December 31, 2022 and 2021 is calculated based on the difference between the exercise price and the fair value of our common stock. The intrinsic value of options exercised in 2022 and 2021 was \$6,864 and \$2,400, respectively.

During 2020, the Company issued 213,624 performance-based awards that vest upon contingent events. The performance condition for these awards were achieved as of June 30, 2021. As a result, the Company recorded compensation expense related to the performance-based awards of \$227 during the year ended December 31, 2021.

The Company estimates the fair value of its option awards to employees and directors using Black-Scholes, which requires inputs and subjective assumptions, including (i) the expected stock price volatility, (ii) the calculation of the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of substantial company-specific historical and implied volatility data of its common stock, the Company has based its estimate of expected volatility on the historical volatility of a group of similar public companies. When selecting these companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry and with historical share price information sufficient to meet the expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

The Company has never paid dividends and does not expect to in the foreseeable future. The expected term of the options granted to employees is derived from the “simplified” method as described in Staff Accounting Bulletin 107 relating to stock-based compensation. The risk-free interest rates for periods within the expected term of the option are based on the U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The Company accounts for actual forfeitures as they occur.

The weighted-average assumptions used to calculate the fair value of stock options granted are as follows:

	December 31, 2022	December 31, 2021
Expected dividend rate	—	—
Expected option term (years)	6.06	6.09
Expected volatility	73.52 %	69.73 %
Risk-free interest rate	2.04 %	1.08 %

Restricted Stock

The following table summarizes restricted stock activity for the year ended December 31, 2022:

	Shares	Weighted Average Grant Date Fair Value
Total Unvested December 31, 2021	681,789	\$ 4.20
Granted	—	—
Vested	(488,758)	1.80
Total Unvested December 31, 2022	193,031	\$ 8.41

Pursuant to certain stock purchase agreements containing vesting and other provisions, the Company has the right to repurchase unvested shares.

As of December 31, 2022, there was \$1,735 of total unrecognized compensation expense related to the unvested restricted stock with time-based vesting terms, which is expected to be recognized over a weighted average period of 1.33 years. All restricted stock vests over a four-year period.

Early-Exercise of Unvested Equity Awards

As part of the merger, the Company assumed a deposit liability from Prior Century. Certain equity award holders early exercised unvested equity awards. The cash received upon early exercise of options is recorded as a deposit liability on the Company’s balance sheet, totaling \$1,584 and \$3,000 as of December 31, 2022 and 2021, respectively.

Note 18—Related party transactions

License and Collaboration Agreements with Shareholder

As part of the Commitment Agreement, the Company acquired licenses and other contracts from Prior Century that were originally entered into by Prior Century and FUJIFILM Cellular Dynamics, Inc. (“FCDI”). FCDI is a shareholder of Century. The acquired licenses and other contracts with FCDI are as follows:

FCDI Licenses

The Company acquired from Prior Century a non-exclusive license agreement with FCDI. The license provides the Company with certain patents and know-how related to the reprogramming of human somatic cells to induce pluripotent stem cells (“iPSCs”) (“License Agreement”). Under this agreement, the Company is required to make certain developmental and regulatory milestone payments as well as royalty payments upon commercialization. Royalties are in the low single digits on the sale of all licensed products.

The Company also acquired from Prior Century an exclusive license agreement with FCDI. The license provides the Company with patents and know-how related to human iPSC exclusively manufactured by FCDI.

The potential development and regulatory milestone payments to be paid by the Company to FCDI are \$6,000.

FCDI Collaboration Agreement

In October 2019, the Company entered into the FCDI Collaboration Agreement with FCDI, whereby FCDI will provide certain services to the Company to develop and manufacture iPSCs and immune cells derived therefrom. FCDI will provide services in accordance with the approved research plan and related research budget. The initial research plan covers the period from the date of execution of the FCDI Collaboration Agreement through March 31, 2022. On July 29, 2022 we amended the FCDI Collaboration Agreement to extend the term through September 30, 2025.

On March 23, 2021, the Company entered into a Manufacturing Agreement with FCDI, or the Manufacturing Agreement, pursuant to which FCDI will provide certain agreed upon technology transfer, process development, analytical testing and cGMP manufacturing services to the Company.

On January 7, 2022, the Company and FCDI entered into a letter agreement (the "Letter Agreement"), which amends each of the FCDI Agreements pursuant to the Company's Research Collaboration and License Agreement with Bristol-Myers Squibb as further discussed in note 18. Pursuant to the Letter Agreement, and in consideration for amending the FCDI Agreements, the Company will pay to FCDI (i) an upfront payment of \$10,000, (ii) a percentage of any milestone payments received by the Company under the FCDI Collaboration Agreement in respect of achievement of development or regulatory milestones specific to Japan, and (iii) a percentage of all royalties received by the Company under the FCDI Collaboration Agreement in respect of sales of products in Japan.

During the years ended December 31, 2022 and 2021, the Company made payments of \$5,100 and \$16,200 and incurred research and development expenses of \$4,900 and \$16,700, and legal fees of \$200 and \$83, respectively, related to the FCDI agreements, recorded within general and administrative expenses in its consolidated statements of operations and comprehensive loss. As of December 31, 2022 and 2021, there was \$0 and \$2,400, respectively, in accounts payable related to the FCDI agreements on the consolidated balance sheets.

Consulting Arrangements with Shareholders

In 2019, the Company entered into arrangements with two shareholders of the Company, wherein the shareholders provide consulting services to the Company. As compensation for the consulting services, the shareholders are entitled to an annual retainer fee, payable quarterly, along with payment of reasonable expenses associated with providing the consulting services. The Company paid \$196 and \$75 related to these consulting arrangements that were included in research and development expenses in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2022 and 2021, respectively. There were no accrued expenses as of December 31, 2022 and 2021.

Note 19—Subsequent Events

On January 2023, the Company's Board of Directors approved and management implemented a new portfolio prioritization and capital allocation strategy. The resulting changes include pausing investment in CNTY-103 for glioblastoma as well as a discovery program in hematologic malignancies. The Company will focus on CNTY-101 and will accelerate key programs, including one follow-on candidate for lymphoma, CNTY-102, and CNTY-107 for Nectin-4+ solid tumors. In addition, the Company will continue its partnered programs with Bristol Myers Squibb with no impact to previous guidance on timelines. The restructuring plan resulted in a reduction

in the Company's workforce of approximately 25%. In addition, lab operations in Seattle and Hamilton will be closed and research activities will be consolidated in Philadelphia.

In connection with the restructuring, the Company incurred approximately \$2,032 of cash-based expenses related to employee severance, benefits and related costs, primarily in the first quarter of 2023. In addition, the Company expects to record a non-cash stock-based compensation charge of approximately \$581 related to modification of equity awards for employees impacted by the restructuring.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, refers to controls and procedures 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 the company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management, with the participation of our Chief Executive Officer and Chief Business Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive Officer and our Chief Business Officer concluded that our disclosure controls and procedures were effective as of December 31, 2022.

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with GAAP. Because of its inherent limitations, our internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with applicable policies or procedures may deteriorate.

Management has assessed the effectiveness of our internal control over financial reporting based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on our evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2022. Management reviewed the results of this assessment with our audit committee.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. For as long as we remain an "emerging growth company" as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business

Startups Act of 2012, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There were no changes to our internal control over financial reporting that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

In connection with the effectiveness of new SEC rules regarding universal proxy cards and a periodic review of our Amended and Restated Bylaws, our Board approved and adopted the Second Amended and Restated Bylaws, or the Amended Bylaws, effective March 16, 2023. The amendments address matters relating to Rule 14a-19 under the Exchange Act, or the Universal Proxy Rules, providing, among other things, that:

- a stockholder delivering a notice of nomination must include a representation that it intends to solicit proxies from stockholders representing at least 67% of the voting power of shares entitled to vote on the election of directors;
- a stockholder delivering a notice of nomination must certify to the Company in writing that it has complied with the Universal Proxy Rules requirements;
- the Company may disqualify a stockholder's nomination if such stockholder fails to satisfy the Universal Proxy Rules requirements;
- a stockholder providing notice pursuant to the Company's advance notice bylaws must inform the Company if the stockholder no longer plans to solicit proxies in accordance with the Universal Proxy Rules; and
- the stockholder to use a proxy card color other than white, which is reserved for the exclusive use of the Board.

The above description of the Amended Bylaws does not purport to be complete and is qualified in its entirety by reference to the full text of the Amended and Restated Bylaws, which is filed as Exhibit 3.2 hereto and incorporated herein by reference.

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 Item 11 of Form 10-K is incorporated by reference to the information contained in our definitive proxy statement for the 2023 annual meeting of stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 of Form 10-K is incorporated by reference to the information contained in our definitive proxy statement for the 2023 annual meeting of stockholders.

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

The information required by Item 12 of Form 10-K is incorporated by reference to the information contained in our definitive proxy statement for the 2023 annual meeting of stockholders.

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

The information required by Item 13 of Form 10-K is incorporated by reference to the information contained in our definitive proxy statement for the 2023 annual meeting of stockholders.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by Item 14 of Form 10-K is incorporated by reference to the information contained in our definitive proxy statement for the 2023 annual meeting of stockholders.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

See Index to the Consolidated Financial Statements on page F-1 of this Annual Report.

(a)(2) Financial Statement Schedules

None, as all information required in these schedules is included in the Notes to the Consolidated Financial Statements.

(a)(3); (b) Exhibits

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

Exhibit Number	Exhibit Description
3.1	Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K (File No. 001-40498) filed on June 25, 2021)
3.2	Second Amended and Restated Bylaws (filed herewith)
4.1	Specimen Common Stock Certificate of Registrant (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A (File No. 333-256648), dated June 14, 2021)
4.2	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K (File No. 001-40498), dated March 17, 2022)
4.3	Investors' Rights Agreement, by and among the Registrant and each of the investors listed on Schedule A thereto, dated February 25, 2021 (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
4.4	Warrant to Purchase Units of Century Therapeutics, LLC, in favor of Hercules Technology Management Co II, Inc., dated September 14, 2020 (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
10.1•	Form of Indemnification Agreement by and between the Registrant and its individual directors and officers (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
10.2•	2018 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
10.3•	Amendment No. 1 to 2018 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
10.4•	Amendment No. 2 to 2018 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
10.5•	Amendment No. 3 to 2018 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
10.6•	Amendment No. 4 to 2018 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
10.7•	Amendment No. 5 to 2018 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
10.8•	2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1/A (File No. 333-256648), dated June 14, 2021)
10.9•	2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1/A (File No. 333-256648), dated June 14, 2021)

- 10.10● Form of Restricted Stock Award Agreement, under the 2018 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
- 10.11● Form of Non-Qualified Stock Option Agreement, under the 2018 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
- 10.12● Form of Incentive Stock Option Agreement, under the 2018 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
- 10.13● Form of Stock Option Grant Notice and Award Agreement, under the 2021 Plan (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
- 10.14● Form of Restricted Stock Unit Grant Notice and Award Agreement, under the 2021 Plan (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
- 10.15* Amended and Restated Option Agreement, by and between Century Therapeutics, Inc. and Bayer HealthCare LLC, dated February 25, 2021 (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
- 10.16* Master Collaboration Agreement, by and between Century Therapeutics, Inc. and FUJIFILM Cellular Dynamics, Inc., dated October 21, 2019 (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
- 10.17 Amendment No. 1 to Master Collaboration Agreement, by and between Century Therapeutics, Inc. and FUJIFILM Cellular Dynamics, Inc., dated July 17, 2020 (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
- 10.18* Amendment No. 2 to Master Collaboration Agreement by and between Century Therapeutics, Inc. and FUJIFILM Cellular Dynamics, Inc., dated March 23, 2021 (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
- 10.19 Amendment No. 3 to Master Collaboration Agreement by and between Century Therapeutics, Inc. and FUJIFILM Cellular Dynamics, Inc., dated March 29, 2021 (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
- 10.20* Amendment No. 4 to Master Collaboration Agreement, by and between Century Therapeutics, Inc. and FUJIFILM Cellular Dynamics, Inc., dated July 29, 2022 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-40498), dated November 10, 2022)
- 10.21 Letter Agreement, by and among Century Therapeutics, Inc., FUJIFILM Cellular Dynamics, Inc. and Wisconsin Alumni Research Foundation, dated July 2, 2019 (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
- 10.22* License Agreement (Differentiation), by and between Century Therapeutics, Inc. and FUJIFILM Cellular Dynamics, Inc., dated September 18, 2018 (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
- 10.23* Amendment No. 1 to License Agreement (Differentiation), by and between Century Therapeutics, Inc. and FUJIFILM Cellular Dynamics, Inc., dated March 23, 2021 (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
- 10.24* License Agreement (Reprogramming), by and between Century Therapeutics, Inc. and FUJIFILM Cellular Dynamics, Inc., dated September 18, 2018 (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
- 10.25* Amendment No. 1 to License Agreement (Reprogramming), by and between Century Therapeutics, Inc. and FUJIFILM Cellular Dynamics, Inc., dated March 23, 2021 (incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
- 10.26* Letter Agreement by and between Century Therapeutics, Inc. and FUJIFILM Cellular Dynamics, Inc., dated January 7, 2022 (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K (File No. 001-40498), dated March 17, 2022)

10.27*	Manufacturing Agreement, by and between Century Therapeutics, Inc. and FUJIFILM Cellular Dynamics, Inc., dated March 23, 2021 (incorporated by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
10.28*	Loan and Security Agreement, by and between Century Therapeutics, Inc. and Hercules Capital, Inc., dated September 14, 2020 (incorporated by reference to Exhibit 10.26 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
10.29	Amendment No. 1 to Loan and Security Agreement, by and between Century Therapeutics, Inc. and Hercules Capital, Inc., dated May 13, 2022 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-40498), dated August 11, 2022)
10.30*	Sublicense Agreement, by and between iCELL Inc. and Century Therapeutics, Inc., dated March 20, 2020 (incorporated by reference to Exhibit 10.27 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
10.31*	License Agreement, by and among the Governing Council of the University of Toronto, the McMaster University and Empirica Therapeutics, dated January 22, 2019 (incorporated by reference to Exhibit 10.28 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
10.32	License Agreement, by and between Inscripta, Inc. and Century Therapeutics, Inc., dated January 1, 2019 (incorporated by reference to Exhibit 10.29 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
10.33*	Research Collaboration and License Agreement, by and between Century Therapeutics, Inc. and Bristol-Myers Squibb Company, dated January 7, 2022 (incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K (File No. 001-40498), dated March 17, 2022)
10.34●	Executive Employment Agreement, by and between the Registrant and Osvaldo Flores, Ph.D., dated May 26, 2021 (incorporated by reference to Exhibit 10.30 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
10.35●	Executive Employment Agreement, by and between the Registrant and Michael Diem, M.D., dated May 26, 2021 (incorporated by reference to Exhibit 10.31 to the Company's Registration Statement on Form S-1 (File No. 333-256648), dated May 28, 2021)
10.36●	Executive Employment Agreement, by and between the Registrant and Luis Borges, Ph.D., dated May 26, 2021 (incorporated by reference to Exhibit 10.33 to the Company's Registration Statement on Form S-1/A (File No. 333-256648), dated June 14, 2021)
10.37●	Executive Employment Agreement, by and between the Registrant and Adrienne Farid, Ph.D., dated May 26, 2021 (incorporated by reference to Exhibit 10.34 to the Company's Registration Statement on Form S-1/A (File No. 333-256648), dated June 14, 2021)
10.38●	Executive Employment Agreement, by and between the Registrant and Gregory Russotti, Ph.D., dated May 26, 2021 (incorporated by reference to Exhibit 10.35 to the Company's Registration Statement on Form S-1/A (File No. 333-256648), dated June 14, 2021)
10.39	Sales Agreement, dated as of July 1, 2022, by and between Century Therapeutics, Inc. and Cowen and Company, LLC (incorporated by reference to Exhibit 1.2 to the Company's Registration Statement on Form S-3 (File No. 333-265975), dated July 13, 2022)
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 1.12 to the Company's Annual Report on Form 10-K (File No. 001-40498), dated March 17, 2022)
23.1	Consent of Ernst & Young LLP, an Independent Registered Public Accounting Firm
31.1	Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer
31.2	Rule 13a-14(a)/15d-14(a) certification of Principal Financial Officer
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101 INS	Inline XBRL Instance 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 (formatted as Inline XBRL and contained in Exhibit 101).

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- Indicates management contract or compensatory plan.
 - * Certain identified information in the exhibit has been omitted because it is the type of information that (i) the Company customarily and actually treats as private and confidential, and (ii) is not material.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CENTURY THERAPEUTICS, INC.

By: /s/ Osvaldo Flores, Ph.D.

Osvaldo Flores, Ph.D.

President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Osvaldo Flores, Ph.D.</u> Osvaldo Flores, Ph.D.	President, Chief Executive Officer and Director (principal executive officer)	March 16, 2023 March 16, 2023
<u>/s/ Michael Diem</u> Michael Diem	Chief Business Officer (principal financial officer)	March 16, 2023
<u>/s/ Douglas Carr</u> Douglas Carr	Vice President Of Finance And Operations (principal accounting officer)	March 16, 2023
<u>/s/ Kimberly Blackwell, M.D.</u> Kimberly Blackwell, M.D.	Director	March 16, 2023
<u>/s/ Cynthia Butitta</u> Cynthia Butitta	Director	March 16, 2023
<u>/s/ Joseph Jimenez</u> Joseph Jimenez	Director, Chairman of the Board	March 16, 2023
<u>/s/ Alessandro Riva, M.D.</u> Alessandro Riva, M.D.	Director	March 16, 2023
<u>/s/ Carlo Rizzuto, Ph.D.</u> Carlo Rizzuto, Ph.D.	Director	March 16, 2023
<u>/s/ Timothy Walbert</u> Timothy Walbert	Director	March 16, 2023
<u>/s/ Daphne Quimi</u> Daphne Quimi	Director	March 16, 2023

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