UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2023

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**: 001-35005**

ASSEMBLY BIOSCIENCES, INC.

(Exact name of registrant specified in its charter)

Delaware	**20-8729264**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

Two Tower Place, 7th Floor
South San Francisco, California 94080
(Address of Principal Executive Offices)

Registrant's telephone number, including area code: **(833) 509-4583**

Securities Registered Pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	**Trading Symbol(s)**	**Name of Exchange on which Registered**
Common Stock, $0.001 Par Value	ASMB	The Nasdaq Global Select Market

Securities Registered Pursuant to Section 12(g) of the Act: None

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

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

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of June 30, 2023, was $60.0 million. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the Nasdaq Global Select Market on June 30, 2023. For purposes of making this calculation only, the registrant has defined affiliates as including only (1) directors, (2) executive officers and (3) certain stockholders, if any, that hold greater than 10% of the voting stock of the registrant, in each case, as of June 30, 2023. Shares of common stock held by other persons, including certain other holders of more than 10% of the registrant's outstanding common stock, if any, have not been excluded from the above calculation in that such persons are not deemed to be affiliates. The determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 22, 2024, there were 5,482,752 shares of the registrant's common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates information by reference to portions of the definitive proxy statement for the Company's Annual Meeting of Stockholders to be held in 2024, to be filed within 120 days of the registrant's fiscal year ended December 31, 2023.

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References to Assembly Biosciences, Inc.

Throughout this Annual Report on Form 10-K, the "Company," "Assembly Bio," "Assembly," "we," "us," and "our," except where the context requires otherwise, refer to Assembly Biosciences, Inc. and its consolidated subsidiaries, and "our board of directors" or "the Board" refers to the board of directors of Assembly Biosciences, Inc.

Forward-Looking Statements

This Annual Report on Form 10-K contains "forward-looking statements" that are subject to certain risks and uncertainties, including, without limitation, those set forth in Part I, Item 1A under the heading "Risk Factors," that could cause actual results to materially differ. Such risks and uncertainties include, among other things:

- our ability to realize the potential benefits of our collaboration with Gilead Sciences, Inc. (Gilead), including all financial aspects of the collaboration and equity investments;
- our ability to initiate and complete clinical studies involving our therapeutic product candidates, including studies contemplated by our collaboration with Gilead, in the currently anticipated timeframes or at all;
- safety and efficacy data from clinical or nonclinical studies may not warrant further development of our product candidates;
- clinical and nonclinical data presented at conferences may not differentiate our product candidates from other companies' candidates; and
- results of nonclinical studies may not be representative of disease behavior in a clinical setting and may not be predictive of the outcomes of clinical studies.

You are urged to consider statements that include the words may, will, would, could, should, might, believes, hopes, estimates, projects, potential, expects, plans, anticipates, intends, continues, forecast, designed, goal or the negative of those words or other comparable words to be uncertain and forward-looking. In particular, forward-looking statements include, but are not limited to, statements regarding the timing of commencement of future clinical studies involving our therapeutic product candidates; and our ability to successfully complete, and receive favorable results in, clinical studies for our product candidates. We intend such forward-looking statements to be covered by the safe harbor provisions contained in Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). Except as required by law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

Item 1. Business

Overview

We are a biotechnology company developing innovative therapeutics targeting serious viral diseases with the potential to improve the lives of patients worldwide. Our pipeline includes two helicase-primase inhibitors (HPI) targeting recurrent genital herpes, an orally bioavailable hepatitis delta virus (HDV) entry inhibitor, a clinical stage capsid assembly modulator (CAM) designed to disrupt the replication cycle of hepatitis B virus (HBV) at several key points with the aim of achieving finite treatment and functional cures and research programs focused on the discovery of therapeutics to treat devastating viral diseases, including a non-nucleoside polymerase inhibitor (NNPI) targeting transplant-related herpesviruses and a small molecule interferon-α (IFN-α) receptor (IFNAR) agonist targeting HBV and HDV.

Our Strategy

Our current business strategy is to apply our deep research and development expertise in virology to bring next-generation therapeutics to patients with serious viral diseases:

- **Recurrent Genital Herpes (HSV-1, HSV-2)** – Advancing two investigational long-acting HPI candidates, (1) ABI-5366 (5366) and (2) ABI-1179 (1179), through Clinical Trial Application (CTA)-enabling studies and into a Phase 1a/1b clinical study in 2024.
- **HDV** – Advancing an orally bioavailable HDV entry inhibitor, ABI-6250 (6250), through CTA-enabling studies and into Phase 1a clinical studies in 2024.
- **Highly Potent Next-Generation HBV Capsid Assembly Modulator** – Advancing our novel next-generation CAM, ABI-4334 (4334), into Phase 1b clinical studies in 2024.
- **Novel Small Molecule Approaches for Transplant-Associated Herpesviruses, HBV and HDV** – Research programs focused on advancing an oral NNPI targeting transplant-associated herpesviruses and a small molecule, IFNAR agonist targeting HBV and HDV towards selection of a development candidate.

We have recruited an accomplished leadership team and research and development organization, with a collective team track record of over 15 approved drugs in viral diseases, including hepatitis. Our collaboration with Gilead Sciences, Inc. (Gilead and the Gilead Collaboration) also brings us an industry leading partner with a shared vision of providing differentiated antiviral treatments to patients. For additional information regarding the Gilead Collaboration, see "Collaboration and License Agreements—Gilead Sciences, Inc."

Development Pipeline Strategy

In addition to the investigational programs that comprise our current pipeline, we will continue leveraging the expertise of our strong research team to identify new viral targets and novel compounds to address significant unmet medical needs.

Our Clinical Programs and CTA-Enabling Programs

Recurrent Genital Herpes/HSV-1 and HSV-2

In August 2022, we introduced our first programs outside of hepatitis. Among our new viral targets is recurrent genital herpes. Genital herpes can be caused by either herpes simplex virus type 1 (HSV-1) or herpes simplex virus type 2 (HSV-2). HSV-1 and HSV-2 are acquired by oral or genital contact either during symptomatic or asymptomatic reactivation of the virus. Both viruses replicate in neurons, where they can remain latent for the rest of the patient's life and periodically reactivate, with the virus spreading and replicating in epithelial tissues. Initial infection can be asymptomatic or can be marked by symptoms, including localized pain and painful lesions. Genital herpes recurrence is common and can cause painful genital lesions that can lead to increased transmission and debilitate patients, and symptoms may become more serious with additional episodes. Additional complications include increased risk of HIV infection, as well as associated psychological stress and isolationary thoughts, depression and suicidal ideation.

Immunocompromised patients may experience more severe and prolonged symptoms due to increased recurrence rates. While genital herpes can be caused by either HSV-1 or HSV-2, recurrences are more likely to be experienced by patients infected by HSV-2.

There are an estimated 800 million people globally with HSV-2, with an estimated 32 million in the United States and 31 million in France, Germany, Italy and Spain (collectively, the EU4) and the United Kingdom (UK). Only approximately 13% of that population is aware of the infection and have been diagnosed. Awareness and diagnostic rates are impacted due to asymptomatic infections and low screening rates in adults and adolescents due to high false positive rates with current diagnostic assays.

HPIs are antiviral agents in development for HSV-1 and HSV-2, with a clinically validated mechanism of action. HPIs inhibit the HSV helicase-primase complex, which is a unique viral enzyme complex without a human homolog, consisting of helicase, primase and cofactor subunits. Both of these subunits have functions that are essential for viral DNA replication and are conserved across HSV-1 and HSV-2. Unlike nucleoside analogs, these compounds do not require phosphorylation by the HSV thymidine kinase (TK) and ongoing viral replication to become active drugs. As a result, HPIs are active immediately upon reactivation of latent HSV-1 and HSV-2. Furthermore, HPIs are active against TK-deficient HSV-1 and HSV-2, which is a major mechanism of resistance to nucleoside analogs.

In February 2023, we announced the nomination of our first herpesvirus development candidate, 5366, a long-acting HPI for treatment of recurrent genital herpes, to progress toward CTA-enabling studies. In connection with the Gilead Collaboration, in October 2023, we acquired the rights to 1179, Gilead's HPI program, which is structurally differentiated from 5366.

Currently, there are three antiviral drugs (all nucleoside analogs) that have been approved in the United States and the EU4/UK for the treatment of genital herpes. No new drugs have been approved to treat genital herpes for more than 25 years. In addition to the approved nucleoside analogs, agents such as local anesthetics or analgesics may be used to alleviate local symptoms of minor pain and discomfort.

Nucleoside analogs can be administered as episodic therapy as individual outbreaks arise or daily as chronic suppressive therapy for those with high post-exposure recurrences. However, these agents are only partially effective at controlling the infection or reducing transmission risk. With current nucleoside analog therapies, only one out of three recurrent genital herpes patients with six or more recurrences per year are able to make it through a year of treatment without a recurrence. There are still high titer (greater than 10^4 HSV-2 DNA copies/mL) shedding episodes under this current standard of care for HSV-2, which can lead to recurrences and transmission of genital herpes.

Based on the limitations of current therapies, we see a path to advancing the treatment paradigm for patients suffering from recurrent genital herpes, To reach that goal, we identified an opportunity to develop a potent, long-acting HPI for recurrent genital herpes, 5366, which has demonstrated a strong nonclinical profile, with low nanomolar potency in vitro against both HSV-1 and HSV-2 clinical isolates, exceptionally low plasma clearance rates in multiple nonclinical models and a projected human half-life of more than seven days. This nonclinical profile has led us to target 5366 for development as a long-acting treatment with the potential to be administered orally or as an injectable.

To date, 5366 has also demonstrated a favorable nonclinical safety profile in Good Laboratory Practice (GLP) toxicology studies, with high safety margins and minimal potential for off-target effects. At the International Herpesvirus Workshop in July 2023, we presented a nonclinical characterization of 5366 for the treatment of recurrent genital herpes. We currently anticipate the initiation of clinical studies with 5366 by mid-2024.

In addition, we are also advancing 1179, a second, structurally-differentiated HPI with single digit nM potency against HSV-1 and HSV-2 and a nonclinical pharmacokinetics (PK) profile strongly supporting a potential long-acting treatment by oral and injectable administration. GLP toxicology studies are underway and clinical studies are expected to begin by the end of 2024.

Our HBV and HDV Programs

The World Health Organization (WHO) estimates that 296 million people worldwide are chronically infected with HBV as of 2019, and 1.5 million new infections occur each year. HBV is a leading global cause of chronic liver disease and liver transplants, and the WHO estimates that 820,000 people died in 2019 from HBV, mostly due to

cirrhosis and hepatocellular carcinoma. Of the 296 million people living with chronic HBV infection, only approximately 30.4 million, or 10.5%, were aware of their infection, and only approximately 6.6 million, or 22%, of those diagnosed received treatment. HBV is a highly prevalent disease that infects more than three times the number of people infected with hepatitis C virus and HIV infections combined, according to the WHO.

HDV is a "satellite virus," because it can only infect people (1) who are already infected with HBV or (2) at the same time as a person is infected with HBV. HDV affects a subset of approximately 12 million HBV infected patients. These patients, which comprise an estimated 4.5% of hepatitis B surface antigen (HBsAg) positive patients, experience a substantially increased disease burden, as they account for 18% of cirrhosis and 20% of hepatocellular carcinoma associated with HBV. HDV is considered the most severe form of hepatitis, as 70% of HDV patients progress to cirrhosis within ten years. While HDV is less prevalent in the United States, it is a significant and serious health problem with inadequate treatment in many parts of Europe, Africa, the Middle East, East Asia and parts of South America. HDV may be significantly underdiagnosed, because there were no HDV-targeted therapies approved until very recently, and the first therapy approved is only approved in the European Union. HDV is known to accelerate disease progression and increase the incidence of liver cirrhosis and liver cancer, which results in higher morbidity and mortality rates than HBV alone.

The current standard of care for chronic HBV infection, nucleos(t)ide analog reverse transcriptase inhibitors (NrtIs), are taken life-long and reduce, but do not eliminate, the virus and result in very low cure rates. No new mechanisms of action (MOA) have been approved for chronic HBV infection in over 25 years. The focus of our HBV program is to improve outcomes and increase the number of patients diagnosed and treated through the development of finite and curative therapies targeting an orthogonal MOA.

The current standard of care treatment for HDV is off-label pegylated IFN-α injected weekly or, in some regions, a large, complex molecule that requires daily injections. There are no approved HDV treatments in the United States, and there is only one approved HDV treatment in Europe. We believe a safe and effective oral small molecule entry inhibitor would be a significant innovation for patients living with HDV, which face a significant and immediate disease burden.

HDV Entry Inhibitor

HDV is a small RNA virus that encodes just two viral proteins and relies on host enzymes as well as the HBsAg from HBV to replicate, which limits the number of HDV-specific antiviral targets. Similar to HBV, HDV utilizes HBsAg to enter hepatocytes by binding the cellular transmembrane protein sodium taurocholate co-transporting peptide (NTCP). NTCP is highly expressed on human hepatocytes, where it serves as one of several proteins involved in the transport of bile acids. The binding of specific small or large molecules to NTCP has been shown to effectively inhibit the interaction of HBsAg with NTCP, which prevents HBV and HDV from infecting hepatocytes.

The inhibition of HBV and HDV infection by molecules that bind NTCP has been demonstrated in vitro, in animal models and clinically. Notably, Bulevirtide, a peptide blocker of NTCP, is the only approved therapy for HDV (approved in the European Union (the EU). The binding of NTCP-targeted HBV/HDV entry inhibitors to NTCP has also been shown to inhibit the transport of certain bile acids into cells, which results in plasma elevations of bile acids; this effect has been well tolerated clinically and may serve as a biomarker of pharmacologically active concentrations of drug in the plasma.

We believe a safe and effective oral small molecule entry inhibitor would be a significant innovation for patients living with HDV and could significantly improve treatment uptake and diagnosis rates, especially when compared with currently available injectable products.

In March 2022, we announced our research program focused on a novel, orally bioavailable small molecule approach to inhibit entry of HBV and HDV by targeting NTCP, and in September 2023, we nominated 6250. In nonclinical studies, 6250 demonstrated low nanomolar potency against all HBV/HDV genotypes, favorable selectivity for NTCP versus other bile acid transporters, good oral bioavailability and a PK profile in nonclinical species projected to support once-daily oral dosing.

At the European Association for the Study of the Liver's (EASL) International Liver Congress™ in June 2023 (EASL 2023) and the International HBV Meeting in September 2023, we presented nonclinical characterization of the

potencies and properties of our novel class of highly potent, small molecule, orally-bioavailable entry inhibitors. We expect to initiate Phase 1a clinical studies of 6250 by the end of 2024.

Capsid Assembly Modulator

HBV is a DNA virus that infects hepatocytes and establishes a reservoir of covalently closed circular DNA (cccDNA), a unique viral DNA moiety that resides in the nucleus of HBV-infected hepatocytes and is associated with viral persistence and chronic infection. No currently approved oral therapies target cccDNA activity directly, which makes molecules that can modulate cccDNA generation or disrupt its function. As a result, we have worked to discover and develop compounds targeting the core protein, a viral protein involved in numerous aspects of the HBV replication cycle, including the generation of HBV cccDNA.

A benchmark for therapeutic agents aiming to decrease cccDNA levels is the use of several key viral antigens as surrogate biomarkers of active cccDNA. The same biomarkers can be used in both primary human hepatocytes and patients. On this basis, our next-generation CAM, 4334, has shown nonclinical proof of principle. In a variety of cell culture models, 4334 has demonstrated the ability to reduce production of viral HBV DNA levels as well as the surrogate markers for cccDNA establishment: HBV e antigen (HBeAg), HBV core-related antigen (HBcrAg) and viral pre-genomic RNA (pgRNA).

As a next-generation CAM, 4334 has been optimized to potently disrupt viral replication (MOA #1) and prevent the establishment and replenishment of new cccDNA (MOA #2). In contrast, while active against MOA #1, first-generation CAMs have not demonstrated adequate potency to sufficiently block cccDNA formation (MOA #2). Further, the current standard of care, NrtIs, impacts the viral life cycle after establishment of cccDNA and can only inhibit production of new viral particles, and it does so incompletely. In mid-2021, we announced the selection of 4334, which was internally discovered, for clinical development. The chemical scaffold of 4334 is novel and distinct from all our prior CAM candidates.

We believe that 4334 has a best-in-class nonclinical profile, with single-digit nanomolar potency against MOA #1 and MOA #2, pan-genotypic activity, an improved resistance profile and a favorable safety profile. Through mechanistic studies presented at multiple conferences, we have demonstrated that 4334 promotes the formation of empty capsids by acceleration of capsid assembly, prevents the formation of cccDNA by disrupting incoming capsids, and prematurely disrupts capsids containing duplex linear DNA, the precursor for integrated HBV DNA. At the International HBV Meeting in September 2023, we presented nonclinical data demonstrating that 4334 impacts HBV DNA integration.

At EASL 2023, we presented safety and PK data from the Phase 1a study. Based on the PK data from the Phase 1a cohorts, plasma trough concentrations (C_{min}) were in multiple-fold excess of the in vitro EC_{50} values for the inhibition of HBV DNA and cccDNA formation at all doses. These data indicate that 4334 has the potential to provide potent inhibition of HBV with once daily dosing, and potential best-in-class activity is projected, with a dose of 200 mg estimated to achieve 175× protein-adjusted EC_{50} ($paEC_{50}$) for DNA replication inhibition and 34× $paEC_{50}$ for the prevention of cccDNA formation.

Treatment-emergent adverse events (AEs) and laboratory abnormalities were mild to moderate, with the majority being mild, and there were no patterns of AEs or laboratory abnormalities noted to be associated with 4334 and no clinically significant electrocardiogram abnormalities were reported.

We expect to initiate Phase 1b clinical studies of 4334 by mid-2024.

Research Programs

Transplant-Associated Herpesviruses

In August 2022, in connection with our announcement of our HPI program, we also introduced our NNPI research program, targeting transplant-associated herpesviruses. In a transplant setting, when patients are experiencing immunosuppression, they are at high risk of uncontrolled viral replication and severe disease brought on by one or more herpesviruses, including cytomegalovirus (CMV), HSV-1, HSV-2 and varicella zoster virus (VZV). Each of these herpesviruses are highly prevalent, as approximately (1) 60% of transplant patients are CMV-positive; (2) 60%

of transplant patients are HSV-positive; and (3) 80% of transplant patients are VZV-positive. These viruses establish lifelong latent infections and frequently reactivate in transplant patients due to the use of immunosuppressive drugs following the transplant. These uncontrolled viral infections increase the risk of severe disease and serious complications, including organ rejection, graft loss and death, and impacted approximately 60,000 patients in 2018 in the United States and EU4/UK.

While there are approved antivirals that are administered in a transplant setting. However, currently approved antivirals are not broad spectrum and pose the risk of potentially serious side effects and drug-drug interactions. As a result of these limitations, we identified an opportunity to develop an oral pan-herpes NNPI for these transplant-associated herpesvirus infections, which could greatly advance treatment. Our research team has discovered multiple chemical series of potent, broad-spectrum herpesvirus polymerase inhibitors. In addition, Gilead exclusively licensed us its NNPI program, and we believe the combined effort will speed candidate nomination and enhance our chance of clinical success.

IFNAR Agonist

In July 2022, we introduced our new research program advancing a novel, small molecule IFNAR agonist designed to selectively activate the IFN-α pathway within the liver and offer the convenience of oral dosing. IFN-α is a subcutaneous injectable immune modulatory therapy approved for HBV that has demonstrated functional cure in some HBV patients, but its poor tolerability profile significantly limits its use. Substantial side effects include flu-like symptoms, cytopenias, serious depression and psychiatric effects. In addition, multiple contraindications limit its use, and it requires weekly injections that result in systemic exposure for up to a year.

By focusing exposure on the liver, our investigational IFNAR agonist program aims to engage IFN-α's validated antiviral and immune modulatory mechanisms, retaining the efficacy of IFN-α while reducing systemic exposure to improve tolerability. At the American Association for the Study of Liver Diseases' (AASLD) The Liver Meeting® in November 2022 (AASLD 2022) and the International HBV Meeting in September 2023, we presented the nonclinical characterization of our novel liver-focused small molecule agonists efficiently inhibiting HBV by activating type 1 interferon signaling, and we presented additional nonclinical data at AASLD's The Liver Meeting® in November 2023. Lead optimization of multiple IFNAR agonists is in progress.

Collaboration and License Agreements

Gilead Sciences, Inc.

On October 15, 2023, we entered into an Option, License and Collaboration agreement (the Gilead Collaboration Agreement) with Gilead pursuant to which Gilead (1) exclusively licensed to us its HPI program and its NNPI program, while retaining opt-in rights to these programs and (2) has an option to take an exclusive license, on a program-by-program basis, to all of our other current and future pipeline programs. During the 12-year collaboration term (subject to payment of certain extension fees) and for a specified period thereafter, Gilead may exercise its opt-in rights, on a program-by-program basis, at one of two timepoints—completion of a certain Phase 1 study or completion of a certain Phase 2 study for the first product within the program—upon payment of an opt-in fee ranging from $45.0 million to $125.0 million per program depending on the type of program and when the option is exercised. Pursuant to the Gilead Collaboration Agreement, Gilead made an $84.8 million upfront cash payment to us.

If Gilead exercises its opt-in right to any current or future program under the collaboration, we are eligible to receive up to $330.0 million in potential regulatory and commercial milestones on that program, in addition to royalties ranging from the high single-digits to high teens, depending on the clinical stage of the program at the time of the opt-in. Following Gilead's exercise of its option for each of our programs, we may opt in to cover 40% of the research and development costs in the United States and share 40% of the profits and operating loss in the United States for products within the program in lieu of receiving milestones and royalties for that program in the United States, unless we later opt out of the cost/profit share for the program. Prior to Gilead's potential exercise of its opt-in, we will be primarily responsible for all discovery, research and development on both our programs and the two Gilead-contributed programs. Following Gilead's opt-in, Gilead will control the further discovery, research, development, and commercialization on any optioned programs. During the term, Gilead will continue to support the collaboration through extension fees of $75.0 million in each of the third, fifth and seventh years of the collaboration.

The Gilead Collaboration Agreement is subject to termination by either party for the other party's uncured, material breach or insolvency. Subject to certain limitations, we and Gilead both have certain termination for convenience rights, upon sufficient prior written notice, with respect to programs that one party in-licenses from the other (subject to Gilead's option rights), and with respect to Gilead, for programs it has option rights to subject to certain time limitations with respect to existing Company programs). Gilead also has a right to terminate the collaborative activities under the Gilead Collaboration Agreement at certain specified points during the collaboration term. Other customary termination rights are further provided in the Gilead Collaboration Agreement.

We and Gilead also entered into a Common Stock Purchase Agreement and an Investor Rights Agreement (together, the Gilead Equity Agreements), pursuant to which Gilead made an upfront equity investment of $15.2 million by purchasing from us 1,089,472 shares of our common stock at a purchase price of $13.92 per share. If we complete an equity financing (or series of financings) by July 15, 2024 that results in at least $30 million of proceeds to us, then, subject to approval by our stockholders (which was obtained on January 31, 2024), we may require Gilead to purchase additional shares of common stock from us in an amount that results in Gilead owning 29.9% of our then-outstanding voting capital stock. If we do not complete the equity financing or do not require Gilead to purchase the additional shares, Gilead may elect to purchase additional shares of common stock from us in an amount that results in Gilead owning 29.9% of our then-outstanding voting capital stock. The purchase price per share for additional shares purchased by Gilead will be equal to the lesser of (1) a 35% premium to the 30-day volume weighted average price immediately prior to the date of purchase or (2) a 35% premium to the 30-day volume weighted average price immediately prior to delivery by Gilead of notice of the anticipated closing date. The Gilead Equity Agreements also include a three-year standstill provision and two-year lockup provision, each with customary exceptions, and provide Gilead with certain other stock purchase rights and registration rights, as well as the right to designate two directors (or, alternatively, board observers at Gilead's election) to our board of directors. In December 2023, Gilead designated Tomas Cihlar, Ph.D. to serve on our board of directors, and in March 2024, Gilead designated Robert D. Cook II to serve on our board of directors.

BeiGene, Ltd.

In July 2020, we entered into a Collaboration Agreement (the BeiGene Agreement) with BeiGene, Ltd. (BeiGene), granting BeiGene an exclusive, royalty-bearing license to develop and commercialize products containing vebicorvir (VBR), ABI-H2158 (2158) and ABI-H3733 (3733) in the People's Republic of China, Hong Kong, Taiwan and Macau (the Territory).

Under the BeiGene Agreement, we and BeiGene will collaborate on development activities with respect to the licensed products in accordance with a mutually agreed upon development plan.

Pursuant to the terms of the BeiGene Agreement, BeiGene paid us an upfront amount of $40.0 million, and we were eligible to receive up to approximately $500.0 million in milestone payments, comprised of up to $113.8 million in development and regulatory and $385.0 million in net sales milestone payments. In September 2021, we discontinued development of 2158 following the observation of elevated alanine transaminase (ALT) levels in the Phase 2 clinical study consistent with drug-induced hepatotoxicity, in July 2022, we discontinued VBR because it did not achieve functional cure or finite treatment in our two- and three-drug combination studies and in March 2023, we prioritized 4334 over 3733 based on data from clinical Phase 1 studies of both candidates and chronic toxicology observation for 3733 and announced that we would seek partnering opportunities for the CAMs. In conjunction with the Gilead Collaboration Agreement, we elected to no longer seek partnering or further development of 3733. As of our discontinuation of 3733 development, there are no remaining products in development that have been licensed to BeiGene.

The BeiGene Agreement also contains provisions such as representations and warranties of the parties, terms as to governance of the collaboration, commercialization and regulatory responsibilities of the parties, and manufacturing and supply, including potential adjustments in the event supply costs exceed certain levels. In addition, during the term of the BeiGene Agreement, neither party will commercialize any competing products in the Territory.

BeiGene may terminate the BeiGene Agreement for convenience at any time upon 90 days' advance written notice to us. The BeiGene Agreement also contains customary provisions for termination by either party, including in the event of breach of the BeiGene Agreement, subject to cure.

Indiana University Research and Technology Corporation

In September 2013, we entered into an exclusive license agreement (the IURTC License Agreement) with Indiana University Research and Technology Corporation (IURTC) pursuant to which we acquired, with rights to sublicense, the rights to develop and commercialize products associated with multiple patents and patent applications covering aspects of our HBV program held by IURTC. As part of this agreement, we were obligated to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones. The aggregate amount of all performance milestone payments under the IURTC License Agreement, should all performance milestones through development be met, was $0.8 million, with a portion related to the first performance milestone having been paid. Under the IURTC License Agreement, we were also obligated to pay IURTC royalties based on net sales of the licensed technology ranging from 0.5% to 1.75%. In addition, under the IURTC License Agreement, we paid annual diligence maintenance fees of $0.1 million. Milestone payments received by IURTC were fully creditable against the annual diligence maintenance fee for the year in which the milestone payments were received.

In January 2024, we notified the Indiana University Innovation and Commercialization Office and IURTC that we had decided to terminate the IURTC License Agreement. The termination of the License Agreement will be effective on April 11, 2024, 90 days following the delivery of the termination notice.

Intellectual Property

We own a published international Patent Cooperation Treaty (PCT) patent application relating to compositions of matter and methods of using 5366 and derivatives/analogs of 5366 to treat HSV. Any patents issuing from this application are expected to expire in 2043. We also own a published PCT application relating to pharmaceutical formulations of 5366. Any patents issuing therefrom are expected to expire in 2043.

We have acquired rights to a published PCT patent application relating to compositions of matter and methods of using 1179 and derivatives/analogs of 1179 to treat HSV. Any patents issuing from this application are expected to expire in 2043. We also have rights to provisional patent applications related to crystalline forms and pharmaceutical formulations of 1179. Any patents issuing therefrom are expected to expire in 2044 and 2045, respectively.

We own an unpublished PCT patent application relating to compositions of matter and methods of using compound 6250 and derivatives/analogs of 6250 to treat HDV and HBV. Any patents issuing therefrom are expected to expire in 2044.

We own a published PCT patent application relating to compositions of matter and methods of using compound 4334 to treat HBV. Any patents issuing therefrom are expected to expire in 2041. We also own published PCT applications relating to processes for preparing 4334 and crystalline forms of 4334. Any patents issuing therefrom are expected to expire in 2042.

Finally, we own provisional, unpublished and published PCT patent applications relating to compositions of matter and method of using HDV/HBV entry inhibitors, IFNAR agonists and pan-herpes NNPIs.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, import and export of pharmaceutical products, such as those we are developing.

U.S. drug approval process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA) and implementing regulations. The process of obtaining regulatory approvals and subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant or sponsor to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, imposition of a clinical hold, issuance of warning letters and untitled letters, product recalls, product seizures, total or

partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal penalties.

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

- completion of nonclinical laboratory tests and animal studies in compliance with the FDA's good laboratory practice (GLP) regulations and applicable requirements for the humane use of laboratory animals or other applicable requirements;
- submission to the FDA of an IND which must become effective before human clinical studies may begin;
- approval by an independent institutional review board (IRB) or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical studies in accordance with good clinical practices (GCP), and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the proposed drug for each indication;
- submission to the FDA of a new drug application (NDA);
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practices (cGMP) requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any potential FDA audits of the clinical trial sites that generated the data in support of the NDA to assure compliance with GCP requirements and integrity of the clinical data;
- compliance with any post-approval requirements, including a risk evaluation and mitigation strategy, or REMS plan, where applicable, and post-approval studies required by the FDA as a condition of approval;
- FDA review and approval of the NDA; and
- compliance with any post-approval requirements, including a REMS, where applicable, and post-approval studies required by the FDA as a condition of approval.

Nonclinical studies and IND

Nonclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of nonclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. Some long-term nonclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. For some products, the FDA may waive the need for certain nonclinical tests. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical studies and places the trial on clinical hold. If an IND or clinical study is placed on clinical hold, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. As a result, submission of an IND may not result in the FDA allowing clinical studies to commence.

Clinical studies

Clinical studies involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical study. Clinical studies are conducted under written study protocols detailing, among other things, the objectives of the study, the

parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical study must review and approve the plan for any clinical study before it commences at that institution, and the IRB must conduct continuing review. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial. Information about certain clinical studies must be submitted within specific timeframes to the National Institutes of Health for public dissemination at www.clinicaltrials.gov. The Food and Drug Omnibus Reform Act (FDORA), which was signed into law on December 29, 2022, made numerous amendments to the FDCA including provisions intended to, among other things, decentralize and modernize clinical trials and enhance diversity in clinical trial populations.

Human clinical studies are typically conducted in three sequential phases, which may overlap or be combined:

- *Phase 1:* The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.
- *Phase 2:* The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- *Phase 3:* The drug is administered to an expanded patient population in adequate and well-controlled clinical studies to generate sufficient data to statistically confirm the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA. Additionally, IND safety reports must be submitted to the FDA and the investigators within 15 calendar days after determining that the information qualifies for reporting. IND safety reports are required for serious and unexpected adverse reactions, findings from animal or *in vitro* testing or other studies that suggest a significant risk to humans, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. In addition, a sponsor must notify the FDA within seven calendar days after receiving information concerning any unexpected fatal or life-threatening suspected adverse reaction. Phase 1, Phase 2 and Phase 3 clinical studies may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

A manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy regarding evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 trial of the investigational drug or, as applicable, 15 days after the drug receives a designation as a breakthrough therapy, Fast Track product, or regenerative advanced therapy. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

Marketing approval

After the completion of required clinical testing, the results of the nonclinical studies and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to a substantial application user

fee, currently $4.0 million and the sponsor of an approved NDA is also subject to an annual program fee currently set at $0.42 million through September 30, 2024. These fees are typically adjusted on October 1 each year.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission before accepting them for filing to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review of NDAs. Under these goals, the FDA has committed to review most original applications for non-priority products within ten months, and most original applications for priority review products, that is, drugs for a serious or life-threatening condition that the FDA determines represent a significant improvement over existing therapy, within six months. For NDAs for novel products, the ten- and six-month time periods runs from the filing date; for all other original applications, the ten- and six-month time periods run from the submission date. The review process may be extended by the FDA for three additional months to consider certain information or clarification regarding information already provided in the submission. Despite these review goals, it is not uncommon for FDA review of an NDA to extend beyond the goal date. The FDA may also refer applications for novel drugs 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. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and integrity of the clinical data submitted. With passage of the FDORA, Congress clarified the FDA's authority to conduct inspections by expressly permitting inspection of facilities involved in the preparation, conduct, or analysis of clinical and non-clinical studies submitted to FDA as well as other persons holding study records or involved in the study process.

After the FDA's evaluation of the NDA and inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter indicates that the NDA will not be approved in its present form and generally outlines the deficiencies in the submission, which may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval and refuse to approve the NDA. Even if the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical studies, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms, including Risk Evaluation and Mitigation Strategies (REMS), which can materially affect the potential market and profitability of the product or impose new labeling, testing or distribution and use requirements. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track designation

The FDA is required to facilitate and expedite the development and review of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the disease or condition. Under the Fast Track program, the sponsor of a new product candidate may request the FDA to designate the product for a specific indication as a Fast Track

product concurrent with or after the filing of the IND for the product candidate. The FDA must determine if the product candidate qualifies for fast track designation within 60 calendar days after receipt of the sponsor's request.

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 product's NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the NDA is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical study process.

Priority review

Under FDA policies, a product candidate may be eligible for priority review, a review generally within a six-month time frame from the time a complete application is received or filed. Products generally are eligible for priority review if they are intended for treatment of a serious or life-threatening disease or condition and provide a significant improvement in safety or effectiveness compared to marketed products in the treatment, diagnosis or prevention of a serious disease or condition.

Accelerated approval

Under the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon 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 (IMM). In clinical studies, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical studies to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA. With the passage of the FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval study and requires sponsors to submit progress reports for required post-approval studies and any conditions required by the FDA until completion or termination of the study. FDORA further enables the FDA to initiate criminal prosecutions for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

Breakthrough therapy designation

A sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies also may be eligible for priority review. 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 decide that the time period for FDA review or approval will not be shortened.

Orphan drugs

Under the Orphan Drug Act, as amended, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally defined as a disease or condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the drug for the disease or condition will be recovered from sales of the product in the United States. Orphan drug designation must be requested before submitting

an NDA or BLA. After the FDA grants orphan drug designation, the identity of the product and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not shorten the duration of the regulatory review and approval process. If a product that has orphan designation subsequently receives the first FDA approval for a particular active ingredient for the disease or condition for which it has such designation, the product is entitled to Orphan Drug exclusivity, which means that the FDA may not approve other applications to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A drug will be considered clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same orphan disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA/BLA application user fee.

Pediatric information

Under the Pediatric Research Equity Act of 2003, as amended, an NDA or supplement to an NDA for drug with certain novel features (e.g., new active ingredient, new indication) must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. A sponsor of a new drug subject to the above pediatric testing requirements also is required to submit to the FDA a pediatric study plan generally 60 days after an end-of-Phase 2 meeting with the agency. Generally, the pediatric data requirements do not apply to products with orphan drug designation.

Other regulatory requirements

Any drug manufactured or distributed by us pursuant to FDA approvals will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval.

The FDA may impose a number of post-approval requirements, including REMS, as a condition of approval of an NDA or BLA. For example, the FDA may require post-marketing testing, including Phase 4 clinical studies, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain cGMP compliance.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;

- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- consent decrees, injunctions or the imposition of civil or criminal penalties.

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

Physician Drug Samples

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act (PDMA) regulates the distribution of drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. In addition, the PDMA sets forth civil and criminal penalties for violations.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical studies, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical studies or marketing of the product in those countries. 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.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we may obtain regulatory approval. Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the approved drugs for a particular indication.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Accordingly, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the trials required to obtain FDA or other comparable regulatory approvals. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development. Further, one payor's determination to provide coverage for a product, if approved, does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of us placing the drug product on the market. Other member states allow companies to fix their own prices for drug products but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any products for which we may receive regulatory approval for commercial sale is dependent on the availability of adequate coverage and reimbursement from government and third-party payors. In addition, the emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. For example the Affordable Care Act of 2010, as amended by, the Health Care and Education Reconciliation Act (collectively, ACA), among other things, imposed an annual fee on any entity that manufactures or imports certain branded prescription drugs, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, and established the Medicare Part D coverage gap discount program. In addition to these provisions, the ACA established a number of bodies whose work may have a future impact on the market for certain pharmaceutical products, including the Patient-Centered Outcomes Research Institute, established to oversee, identify priorities in, and conduct comparative clinical effectiveness research, and the Center for Medicare and Medicaid Innovation within the Centers for Medicare and Medicaid Services, established to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been executive, judicial, and Congressional challenges to certain aspects of the ACA. For example, former President Trump issued directives designed to delay the implementation of certain PPACA provisions or otherwise circumvent requirements for health insurance mandated by the PPACA, and Congress has considered legislation that would repeal, or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act, effectively repealed the individual health insurance mandate, which is considered a key component of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Another case challenging the PPACA's requirement that insurers cover certain preventative services is currently pending before the Fifth Circuit Court of Appeals.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 2021, due to the COVID-19 pandemic. Further, in January 2013, then President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent United States Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the Inflation Reduction Act of 2022, or IRA, enacted on August 16, 2022, seeks to reduce prescription drug costs by, among other provisions, allowing Medicare to negotiate prices for certain high-cost prescription drugs in Medicare Parts B and D, imposing

an excise tax on pharmaceutical manufacturers that refuse to negotiate pricing with Medicare, and requiring inflation rebates to limit annual drug price increases in Medicare. These provisions began taking effect progressively starting in 2023, including an initial group of ten drugs that HHS selected for the first cycle of Medicare drug price negotiations in 2024. Beginning in 2025, the IRA also eliminates the coverage gap under Medicare Part D by significantly lowering the enrollee maximum out-of-pocket cost and imposing on new manufacturer discount program. The Centers for Medicare & Medicaid Services (CMS) has begun to implement aspects of the Inflation Reduction Act and has released guidance addressing the Medicare Part B and Medicare Part D inflation rebate provisions of the Inflation Reduction Act; however, various industry stakeholders, including certain pharmaceutical companies and industry trade organizations have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. The impact of these judicial challenges and future government reform measures on us and the pharmaceutical industry as a whole is unclear. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights.

In addition, in September 2020, the FDA issued a final rule that sets up a legal framework for allowing the importation of certain prescription drugs from Canada, and the CMS issued guidance that addresses the treatment of certain imported drugs under the Medicaid Drug Rebate Program. On January 5, 2024, the FDA authorized the state of Florida's Section 804 Importation Program, which is the first major step in allowing the state to import certain prescription drugs from Canada. If the program is ultimately approved, it will be the first such program authorized in the United States.

Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. These measures could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing. We expect that additional state and federal 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 reduced demand for our product candidates or additional pricing pressures.

Other Healthcare Laws

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice (DOJ), and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, the Company's business practices, including its research and sales, marketing and scientific/ educational grant programs may be required to comply with federal and state fraud and abuse laws, false claims laws, the data privacy and security provisions of the Health Insurance Portability and Accountability Act (HIPAA), federal transparency requirements and similar state laws, each as amended. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and patients, prescribers, purchasers, and formulary managers on the other;

- federal civil and criminal false claims laws, including the federal False Claims Act, which can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws that prohibit individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; making a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims;

- HIPAA, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal false statements statute prohibits making a false statement to an agent or agency of the federal government in connection with certain federal matters;

- the federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments or other transfers of value made to physicians, certain other healthcare professionals (such as nurse practitioners and physicians' assistants, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- federal government price reporting laws, which require companies to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. In addition, some states require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other healthcare providers. There also are state laws that require the reporting of marketing expenditures or drug pricing, including information pertaining to and justifying price increases, state and local laws that require the registration of pharmaceutical sales representatives or other state or local licensure, state laws that prohibit various marketing-related activities, such as

the provision of certain kinds of gifts or meals, and state laws that require the posting of information relating to clinical trials and their outcomes. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

In addition, regulators globally are also imposing greater monetary fines for privacy violations. In respect of our engagement of European contract research organizations (CROs) in the context of clinical trials, the General Data Protection Regulation (EU GDPR), which went into effect on May 25, 2018, applies. The EU GDPR applies to any company established in the EU as well as to those outside the EU if they collect and use personal data in connection with the offering goods or services to individuals in the EU or the monitoring of their behavior. The EU GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and onerous new obligations on services providers. Noncompliance with the EU GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. In addition, violations of the EU GDPR could result in regulatory investigations, reputational damage, orders to cease and/or change our processing activities, enforcement notices and/or assessment notices (for compulsory audit). We may also face civil claims, including representative actions and other class action type litigation (where individuals have suffered harm), potentially amounting to significant compensation or damages liabilities as well as associated costs, diversion of internal resources and reputational harm. This is as the EU GDPR 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.

The EU GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the EU GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the EU GDPR, including as implemented by individual countries. In July 2020, the EU-US Privacy Shield was invalidated as a valid personal data transfer mechanism and on June 27, 2021, the European Commission published a new set of modular standard contractual clauses (New SCCs). The New SCCs must be used for all relevant transfers of personal data outside the European Economic Area (EEA) (since December 27, 2022). On July 11, 2023, the European Commission entered into force its adequacy decision for the EU-US Data Privacy Framework (a new framework for transferring personal information from the EEA to the United States), having determined that such framework ensures that the protection of personal information transferred from the EEA to the US will be comparable to the protection offered in the EU. However, this decision will likely face legal challenges and ultimately may be invalidated by the Court of Justice of the European Union (CJEU) just as the EU-US Privacy Shield was. The cross-border data transfer landscape in the EEA is continually developing, and we are monitoring these developments. We may, in addition to other impacts, experience additional costs associated with increased compliance burdens and be required to engage in new contract negotiations with third parties that aid in processing data on our behalf or localize certain data.

California enacted the California Consumer Privacy Act (CCPA), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. Additionally, the California Privacy Rights Act (CPRA), which went into effect on January 1, 2023, imposes additional obligations on companies covered by the legislation and expands consumers' rights with respect to certain sensitive personal information, among other things. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. Other states, including Virginia and Colorado have similarly passed data privacy laws that will regulate how businesses collect and share personal information.

New Legislation and Regulations

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing, marketing, and reimbursement status of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether

further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations will be changed or what the effect of such changes, if any, may be.

Competition

The pharmaceutical and biotechnology industry is very competitive, and the development and commercialization of new drugs is influenced by rapid technological developments and innovation. We face competition from several companies developing and commercializing products that will be competitive with our drug candidates, including large pharmaceutical and smaller biotechnology companies. Additionally, new entrants may potentially enter the market. Potential competitors include Johnson & Johnson, Roche, GlaxoSmithKline plc, Enanta Pharmaceuticals, Inc., HEC Pharma, Arbutus Biopharma, Vir Bio, Aligos Therapeutics, AiCuris Anti-infective Cures AG and Qilu Pharmaceutical, among others. Additionally, we may face competition from currently available HBV treatments. Some of the competitive development programs from these companies may be based on scientific approaches that are similar to our approach, and others may be based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization of products similar to ours or that otherwise target indications that we are pursuing.

Manufacturing

We currently rely on third-party manufacturers to supply the quantities of our investigational product candidates used in our clinical and nonclinical studies. We currently have no plans to establish any manufacturing facilities for our product candidates.

Human Capital Management

As of December 31, 2023, we had 65 total employees and contracts with a number of temporary contractors, consultants and CROs. The majority of our employees work out of our facility in South San Francisco, California. We also have a small number of remote employees spread across the United States and one remote employee in the UK.

We continually evaluate our needs and make strategic choices regarding whether to hire internal teams or outsource certain functions to CROs or contract manufacturing organizations (CMOs), as appropriate. We currently outsource our clinical study management to various CROs and utilize certain CMOs to manufacture both the drug substance and the drug product used in our ongoing and planned clinical studies.

We compete with both large and small companies in our industry for a limited number of qualified applicants to fill highly specialized needs. We generally target our base salaries and annual performance-based cash bonuses at the 50th percentile of our peers and our long-term equity incentive compensation, which all employees receive, between the 50th and 75th percentiles of our peers. In certain circumstances, we offer compensation above these levels, based on a candidate's experience, criticality, amount of responsibility and either individual or Company-wide performance. We routinely review our employees' base salaries to ensure they remain market competitive. Both annual performance-based cash bonuses and long-term equity compensation increase as a percentage of total compensation based on employees' levels of responsibility. We also offer comprehensive benefits packages to all of our employees, including: 100% Company-covered medical, dental and vision coverage for employees and their families; a 401k program with a Company match; a comprehensive employee assistance program, an employee stock purchase plan; and paid family leave.

A large majority of our employees have advanced degrees, and we also offer an educational assistance program that reimburses employees up to a maximum amount per year for courses that directly enhance his or her area of professional work or contribute to his or her immediate career growth. This program demonstrates our commitment to analytical growth, enhanced knowledge and professional development.

Reverse Stock Split

On September 27, 2023, we received a letter from the Listing Qualifications Department of the Nasdaq Stock Market notifying us that, because the bid price for our common stock had closed below $1.00 per share for the prior 30 consecutive business days, we were not in compliance with Nasdaq Listing Rule 5450(a)(1), which is the minimum bid price requirement for continued listing on the Nasdaq Global Select Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided a 180-calendar day period, or until March 25, 2024, to regain

compliance with the minimum bid price requirement. To regain compliance with the Nasdaq Listing Rules, on January 31, 2024, our stockholders approved a reverse stock split of our common stock at a range of ratios between 1-for-7 to 1-for-17, and our board of directors approved the implementation of a reverse stock split at a ratio of 1-for-12 shares of our common stock (the Reverse Stock Split). The Reverse Stock Split was effective as of February 9, 2024, our common stock began trading on the Nasdaq Global Select Market on an as-split basis on February 12, 2024, and the Company regained compliance with the minimum bid price requirement of the Nasdaq Listing Rules on February 27, 2024, by having the closing bid price of our common stock exceed $1.00 for a minimum of ten consecutive trading days during the compliance period.

All share and per share amounts of our common stock presented in this Annual Report on Form 10-K have been retroactively adjusted to reflect the 1-for-12 Reverse Stock Split.

Corporate History

We were incorporated in Delaware in October 2005 under the name South Island Biosciences, Inc. (which was changed to Ventrus Biosciences, Inc. in April 2007). On July 11, 2014, we acquired Assembly Pharmaceuticals, Inc., a private company, through a merger with our wholly owned subsidiary (the Merger). In connection with the Merger, we changed our name from Ventrus Biosciences, Inc. to Assembly Biosciences, Inc.

Corporate Information

Our principal executive office is at Two Tower Place, 7th Floor, South San Francisco, California 94080. Our telephone number is (833) 509-4583.

Available Information

Our website address is www.assemblybio.com. We routinely post, or have posted, important information for investors on our website in the “Investors” section. We use this website as a means of disclosing material information in compliance with our disclosure obligations under Regulation FD. Accordingly, investors should monitor the “Investors” section of our website, in addition to following our press releases, Securities and Exchange Commission (SEC) filings, presentations and webcasts. We make available free of charge through our website our press releases, Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after electronically filed with or furnished to the SEC.

The information contained on our website is not a part of, and should not be construed as being incorporated by reference, into this report.

The reports filed with the SEC by us and by our officers, directors and significant stockholders are available for review on the SEC’s website at www.sec.gov.

Item 1A. Risk Factors

You should carefully consider the following risk factors, together with all other information in this report, including our consolidated financial statements and notes thereto, and in our other filings with the SEC. If any of the following risks, or other risks not presently known to us or that we currently believe to not be material, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

Risks Related to Our Business

We have no approved products and depend on the future success of the product candidates in our research and development pipeline. We cannot be certain that we or our collaborators will be able to obtain regulatory approval for, or successfully commercialize, product candidates from our current pipeline or any other product candidates that we may subsequently identify, license or otherwise acquire.

We and our collaborators are not permitted to market or promote any products in the United States, Europe, China or other countries before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for our current product candidates. We have not submitted a new drug application (NDA) to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so in the near future.

All of our product candidates are in clinical development or in varying stages of nonclinical development. Data supporting our drug discovery and nonclinical and clinical development programs are derived from laboratory studies, nonclinical studies and Phase 1 clinical studies. It may be years before the larger, pivotal studies necessary to support regulatory approval of our current product candidates are completed, if ever.

In addition to our current product pipeline, we may identify, license or otherwise acquire rights to other technologies or product candidates. Any such transactions would involve numerous risks, and we may be unsuccessful in entering into any such transactions or developing any such technologies or product candidates.

For these reasons, our drug discovery and development may not be successful, and we may be unable to continue clinical development of our product candidates and may not generate product approvals or product revenue, any of which could have a material adverse impact on our business, results of operations and financial condition.

We are not currently profitable and might never become profitable, and we will need additional financing to complete the development of any product candidates and fund our activities into the future.

We do not have any approved products, and we have a history of losses. We expect to continue to incur substantial operating and capital expenditures to advance our current product candidates through clinical development, continue research and discovery efforts to identify potential additional product candidates and seek regulatory approvals for our current and future product candidates. All operations and capital expenditures will be funded from cash on hand, securities offerings, debt financings and payments we may receive from out-licenses, collaborations or other strategic arrangements. Elevated worldwide inflation rates that began in mid-2021 and continue to persist may also exacerbate the substantial operating and capital expenditures that we face to advance our current and future product candidates.

There is no assurance that we will be successful in raising any necessary additional capital on terms that are acceptable to us, or at all, particularly due to the well-documented, ongoing sector-wide weakness in the biotech markets that began in early 2021. If we are unable to develop and commercialize any product candidates and generate sufficient revenue or raise capital, we could be forced to reduce staff, delay, scale back or discontinue product development and clinical studies, sacrifice attractive business opportunities, cease operations entirely and sell, or otherwise transfer, all or substantially all of our remaining assets, which would likely have a material adverse impact on our business, results of operations, financial condition and share price.

We expect our collaboration with Gilead to be a critical part of the development, manufacture and commercialization of our product candidates. If this collaboration is unsuccessful, our business could be adversely affected.

In October 2023, we entered into the Gilead Collaboration Agreement with Gilead, whereby Gilead exclusively licensed to us its HPI program and NNPI program, while retaining opt-in rights to these programs, and will have an option to take an exclusive license, on a program-by-program basis, to all of our other current and future pipeline

programs during the collaboration term. In connection with the entry into the Gilead Collaboration Agreement, we and Gilead also entered into a common stock purchase agreement and an investor rights agreement. Our agreements and relationship with Gilead pose a number of risks, including, but not limited to, the following:

- Conflicts may arise between us and Gilead, such as conflicts regarding the indications to pursue or concerning the clinical data supporting an opt-in decision, the commercial potential of any optioned investigational products, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. Any such conflicts could slow or prevent the development or commercialization of our investigational products.
- If the collaboration with Gilead does not result in the successful development and commercialization of products or if Gilead terminates the Gilead Collaboration Agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our investigational products could be delayed and we may need additional resources to develop our investigational products.
- We will be heavily dependent on Gilead for further development and commercialization of the investigational products from the programs that it opts into.
- We may not be successful in this collaboration due to various other factors, including our ability to demonstrate proof of concept in one or more clinical studies so that Gilead will exercise its option to these programs. In addition, even if we demonstrate clinical proof of concept of a candidate, Gilead may choose not to exercise its option.
- Gilead has the right to designate two directors for appointment to our board of directors pursuant to the terms of the investor rights agreement and owns approximately 19.9% of our outstanding common stock. Gilead also has the right to acquire additional shares from us, and in the open market, up to an amount resulting in Gilead owning a total of 35% of our outstanding common stock. As a result, Gilead may be able to exert significant influence over us.
- Gilead could independently develop, or develop with third parties, products that compete directly or indirectly with our investigational products if Gilead believes that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- Because Gilead has an option to all of our current, and future, pipeline programs during the collaboration term, it may be difficult for us to enter into new collaborations.

Nonclinical and clinical studies required for our product candidates are expensive and time-consuming and may fail to demonstrate the level of safety and efficacy necessary for product approval.

Before we or any commercial partners can obtain FDA approval (or other foreign approvals) necessary to sell any of our product candidates, we must show that each potential product is safe and effective. To meet these requirements, we must conduct extensive nonclinical and sufficient, well-controlled clinical studies.

The results of laboratory and nonclinical studies may not be representative of disease behavior in a clinical setting and may not be predictive of the outcomes of our clinical studies. In addition, the results of early clinical studies of product candidates may not be predictive of the results of later-stage clinical studies.

Conducting nonclinical and clinical studies is a lengthy, time consuming and expensive process. The length of time varies substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more. In addition, failure or delays can occur at any time during the nonclinical and clinical study process, resulting in additional operating expenses or harm to our business.

The commencement and rate of completion of clinical studies might be delayed by many factors, including, for example:

- delays in reaching agreement with regulatory authorities on study design;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical study sites;
- failure to demonstrate efficacy or the emergence of unforeseen safety issues;

- insufficient quantities of qualified materials under current good manufacturing practice (cGMP) for use in clinical studies due to manufacturing challenges, delays or interruptions in the supply chain;
- slower than expected rates of patient recruitment or failure to recruit a sufficient number of eligible patients, which may be due to a number of reasons, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the design of the clinical study, and other potential drug candidates being studied;
- delays in patients completing participation in a study or return for post-treatment follow-up for any reason, including, product side effects or disease progression;
- modification of clinical study protocols;
- delays, suspension, or termination of clinical studies by the institutional review board or ethics committee responsible for overseeing the study at a particular study site; and
- government or other regulatory agency delays or clinical holds requiring suspension or termination of our clinical studies due to safety, tolerability or other issues related to our product candidates.

The failure of nonclinical and clinical studies to demonstrate safety and effectiveness of a product candidate for the desired indications, whether conducted by us or by a CRO, would harm the development of that product candidate and potentially other product candidates. This failure could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or failure of, our nonclinical studies or clinical studies could delay, or preclude, the filing of our NDAs and comparable applications with the FDA and foreign regulatory agencies, as applicable, and materially harm our business, prospects, financial condition and results of operations.

We rely on CROs to conduct some of our nonclinical and clinical studies due to our lack of suitable facilities and resources. In addition, parts of our business are reliant on CROs, vendors, suppliers and other service providers in locations outside of the United States, including China.

We do not have sufficient facilities or resources to conduct all our anticipated nonclinical and clinical studies internally. As a result, we contract with CROs to conduct a significant portion of the nonclinical and clinical studies required for regulatory approval for our product candidates. Our reliance on CROs reduces our control over these activities but does not relieve us of our responsibilities. For example, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, including, in the case of clinical studies, good clinical practices, even if the study is conducted by a CRO. In the event CROs fail to perform their duties in such a fashion or we are unable to retain or continue with CROs on acceptable terms, we may be unable to complete our clinical studies and may fail to obtain regulatory approval for our product candidates.

In addition, these CROs may also have relationships with other entities, some of which may be our competitors. CRO personnel are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our clinical and nonclinical studies. If these CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our research, nonclinical or clinical studies may be extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates, any of which could materially harm our business, prospects, financial condition and results of operations.

Furthermore, we are exposed to a number of risks related to our CROs, vendors, suppliers and other service providers that are located outside of the United States, many of which may be beyond our control. These risks include:

- business interruptions resulting from geopolitical actions such as the war between Russia and Ukraine, the Israel-Hamas war, as well as tariffs, other wars, acts of terrorism, natural disasters or outbreaks of disease;
- different regulatory requirements for drug approvals or increased scrutiny on CROs located in foreign countries, including China;
- different standards of care in various countries that could complicate the evaluation of our product candidates;

- different U.S. and foreign drug import and export rules;
- different reimbursement systems and different competitive drugs indicated to treat the indication for which our product candidates are being developed;
- reduced protection for intellectual property rights in certain countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- compliance with the United States Foreign Corrupt Practices Act (the FCPA) and other anti-corruption and anti-bribery laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes; and
- foreign currency fluctuations and compliance with foreign currency exchange rules, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country.

Top-line or preliminary data may not accurately reflect the final results of a particular study.

We may publicly disclose top-line or preliminary data based on analysis of then-available efficacy, tolerability, PK and safety 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. We also make assumptions, estimates, calculations and conclusions as part of our data analyses, and we may not have received or had the opportunity to fully and carefully evaluate all data prior to release. As a result, the top-line or preliminary results that we report may differ from final results of the same studies or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Top-line data also remains subject to audit and verification procedures that may result in the final data differing materially from previously published preliminary data. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

In addition to top-line or preliminary results, the information that we may publicly disclose regarding a particular nonclinical or clinical study is based on extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. In addition, any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the top-line or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with, or do not accept, the data or conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed or delayed, which could harm our business, financial condition, operating results or prospects.

We rely on third parties to formulate and manufacture our product candidates and products that we study in combination with our product candidates. Our use of third parties may increase the risk that we will not have sufficient quantities of our product candidates or other products on time or at an acceptable cost.

We rely on third-party manufacturers to supply the quantities of our investigational product candidates used in our clinical and nonclinical studies. If any product candidate we develop or acquire in the future receives FDA or other regulatory approval, we expect to continue our reliance on one or more third-party contractors to manufacture our products. If, for any reason, we are unable to rely on any third-party sources we have identified to manufacture our product candidates, we would need to identify and contract with additional or replacement third-party manufacturers to manufacture drug substance and drug product for nonclinical, clinical and commercial purposes. We may be unsuccessful in identifying additional or replacement third-party manufacturers, or in negotiating acceptable terms with any that we do identify. If we are unable to establish and maintain manufacturing capacity, the development and sales of our products and our financial performance may be materially and adversely affected.

We are exposed to the following risks with respect to the manufacture of our product candidates:

- We will need to identify manufacturers for commercial supply on acceptable terms, which we may be unable to do because the number of potential manufacturers is limited, and the FDA must evaluate and approve any new or replacement contractor.

- Any third-party manufacturers with whom we contract might be unable to formulate and manufacture our product candidates in the volume and quality required to meet our nonclinical, clinical and, if approved, commercial needs in a timely manner.
- Any third-party manufacturers with whom we contract might not perform as agreed or might not remain in the contract manufacturing business for the time required to supply our products.
- One or more of any third-party manufacturers with whom we contract could be foreign, which increases the risk of shipping delays and adds the risk of import restrictions.
- We do not have complete control over, and cannot ensure, any third-party manufacturers' compliance with cGMP and other government regulations and corresponding foreign requirements, including periodic FDA and state regulatory inspections.
- We may be required to obtain intellectual property rights from third parties to manufacture our product candidates, and if any third-party manufacturer makes improvements in the manufacturing process for our product candidates, we may not own, or may have to share, the intellectual property rights to the innovation.
- We may be required to share our trade secrets and know-how with third parties, increasing risk of misappropriation or disclosure of our intellectual property by or to third parties.
- When contracting with third-party manufacturers, we might compete with other companies for access to these manufacturers' facilities and might be subject to manufacturing delays if the manufacturers give other clients higher priority than we are given.

Each of these risks could delay our development efforts, nonclinical studies and clinical studies or the approval, if any, of our product candidates by the FDA or applicable non-U.S. regulatory authorities and the commercialization of our product candidates. This could result in higher costs or deprive us of potential product revenues and materially harm our business, financial condition and results of operations.

If we lose key management personnel and cannot recruit and retain similarly qualified replacements, our business may materially suffer.

We are highly dependent on the services of our executive officers. Our employment agreements with our executive officers do not ensure their retention. We do not currently maintain, nor do we intend to obtain in the future, "key person" life insurance that would compensate us in the event of the death or disability of any of the members of our management team. Our executive officers are critical to our success, and unanticipated loss of any of these key employees could have a material adverse impact on our business, financial condition and results of operations.

Our collaboration partners might delay, prevent or undermine the success of our product candidates.

Our operating and financial strategy for the development, nonclinical and clinical testing, manufacture and commercialization of drug candidates heavily depends on collaborating with corporations, academic institutions, licensors, licensees, and other parties. However, there can be no assurance that we will successfully establish or maintain these collaborations. If a collaboration is terminated, replacement collaborators might not be available on attractive terms, or at all.

The activities of any collaborator, including Gilead, will not be within our control and might not be within our power to influence. There can be no assurance that any collaborator will perform its obligations to our satisfaction or at all, that we will derive any revenue or profits from these collaborations, or that any collaborator will not compete with us. If any collaboration, including the Gilead Collaboration, is unsuccessful, we might require substantially greater capital to undertake development and marketing of our proposed products and might not be able to develop and market these products effectively, if at all. In addition, if Gilead does not opt-in to a program, it might lead to significant delays in introducing proposed products into certain markets and/or reduced sales of proposed products in such markets.

We may not be successful in establishing and maintaining collaborations, which could adversely affect our ability to develop certain of our product candidates.

Developing pharmaceutical products, conducting clinical studies, obtaining regulatory approval and commercializing those products are expensive and lengthy undertakings that require significant resources and expertise. We may seek to enter into collaborations, including licensing or partnering arrangements, with other companies to support the development and commercialization of any or multiple of our programs that Gilead declines to opt into or to obtain financing or share costs on these programs. If we are unable to enter into such collaborations on acceptable terms, if

at all, we may be unable to advance certain of our product candidates through further nonclinical or clinical development. We expect to face competition in seeking appropriate partners. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements for the development of our product candidates that Gilead declines to opt into.

If we are unable to reach agreement on favorable terms with a suitable collaboration partner for any of our product candidates that Gilead declines to opt into, we may need to limit the number of our product candidates to advance through further nonclinical or clinical development. Failure to achieve such successful collaborations would limit our options for support of the development and commercialization of our programs and for financing and would likely have a material adverse impact on our business, results of operations, financial condition and share price.

We rely on data provided by third parties that has not been independently verified and could prove to be false, misleading, or incomplete.

We rely on third-party vendors, scientists, investigators and collaborators to provide us with significant data and other information related to our projects, nonclinical studies and clinical studies, and our business. If these third parties provide inaccurate, misleading, or incomplete data, our business, prospects, and results of operations could be materially and adversely affected.

Significant disruptions of information technology systems or breaches of data security, including cybersecurity incidents, could materially and adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form and are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have outsourced elements of our information technology infrastructure and, as a result, a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks, cybersecurity incidents or cyber intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a cybersecurity incident or security breach or disruption, particularly through cyberattacks or cyber intrusion, has escalated as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities or incidents could be significant, and our efforts to address these problems may not be successful. If unsuccessful, these problems could cause interruptions, delays, cessation of service and other harm to our business and our competitive position, including material disruption of our product development programs. For example, any loss of clinical study data from completed or ongoing or planned clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

If a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal, state and non-U.S. privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Clinical Health Act of 2009, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission, state breach notification law and the EU GDPR. We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

Research, development and commercialization goals may not be achieved in the timeframes that we publicly estimate, which could have an adverse impact on our business and could cause our stock price to decline.

We set goals and make public statements regarding our expectations on timing of certain accomplishments, developments and milestones under our research and development programs. The actual timing of these events can vary significantly due to a number of factors, including, the amount of time, effort and resources committed to our programs by us and any collaborators and the uncertainties inherent in the clinical development and regulatory approval process. As a result, there can be no assurance that we or any collaborators will initiate or complete clinical

development activities, make regulatory submissions or receive regulatory approvals as planned or that we or any collaborators will be able to adhere to our current schedule for the achievement of key milestones under any of our programs. If we or any collaborators fail to achieve one or more of the milestones as planned, or Gilead does not opt-in to any of our programs, our business could be materially and adversely affected, and the price of our common stock could decline.

Developments by competitors might render our product candidates or technologies obsolete or non-competitive.

The pharmaceutical and biotechnology industries are intensely competitive. In addition, the clinical and commercial landscapes for recurrent genital herpes, HDV, HBV and transplant-related herpesviruses are rapidly changing; we expect new data from commercial and clinical-stage products to continue to emerge. We compete with organizations, some with significantly more resources, who are developing competitive product candidates. If our competitors develop effective treatments for recurrent genital herpes, HDV, HBV, transplant-related herpesviruses or any other indication or field we might pursue, and successfully commercialize those treatments, our business and prospects could be materially harmed.

Other companies with products using the same or similar mechanisms of action as ours may produce negative clinical data, which would adversely affect public and clinical communities' perceptions of our product candidates, and may negatively impact regulatory approval of, or demand for, our potential products.

Negative data from clinical studies using a competitor's product candidates with the same or similar mechanisms of action as ours could adversely impact the perception of the therapeutic use of our product candidates and our ability to enroll patients in clinical studies.

The clinical and commercial success of our potential products will depend in part on the public and clinical communities' acceptance of novel classes of product candidates. Moreover, our success depends upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which more clinical data may be available. Adverse events in our nonclinical or clinical studies or those of our competitors or of academic researchers utilizing the same mechanisms of action as our product candidates, even if not ultimately attributable to our product candidates, and any resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for our product candidates that are approved, if any, and a decrease in demand for any such products.

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

We have net operating loss carryforwards due to prior period losses generated before January 1, 2024 which if not utilized will begin to expire in 2027 for net operating loss carryforwards prior to 2018. If we are unable to generate sufficient taxable income to utilize our net operating loss carryforwards, pre-2018 carryforwards could expire unused and be unavailable to offset future income tax liabilities.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period) is subject to annual limitations on its ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes. We have experienced ownership changes in the past, and recent and future equity issuances may result in additional ownership change. Accordingly, some of our net operating losses or credits could expire unutilized, and our ability to utilize our net operating losses or credits to offset U.S. federal taxable income could be limited, which would result in increased future tax liability to us. We may also be subject to similar limitations at the state level.

Risks Related to Our Regulatory and Legal Environment

We are and will be subject to extensive and costly government regulation and the failure to comply with these regulations may have a material adverse effect on our operations and business.

Our product candidates are subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice, state and local governments, and their respective foreign equivalents. Both before and after approval of any product, we and our collaborators, suppliers, contract manufacturers and clinical investigators are subject to extensive regulation by governmental authorities in the United States and other countries, covering, among other things, testing, manufacturing, quality control, clinical studies, post-marketing studies, labeling, advertising, promotion, distribution, import and export, governmental pricing, price reporting and rebate requirements. Failure to comply with applicable requirements could result in one or more of the following actions:

warning or untitled letters; unanticipated expenditures; delays in approval or refusal to approve a product candidate; voluntary or mandatory product recall; product seizure; interruption of manufacturing or clinical studies; operating or marketing restrictions; injunctions; criminal prosecution and civil or criminal penalties, including fines and other monetary penalties; exclusion from federal health care programs such as Medicare and Medicaid; adverse publicity; and disruptions to our business.

If we or our collaborators obtain regulatory approval for a particular product, the approval might limit the intended medical uses for the product, limit our ability to promote, sell, and distribute the product, require that we conduct costly post-marketing surveillance, and/or require that we conduct ongoing post-marketing studies. Once obtained, any approvals might be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue. If we, our collaborators, our contractors or our contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in delays in the approval of applications or supplements to approved applications, refusal by a regulatory authority (including the FDA) to review pending market approval applications or supplements to approved applications, untitled letters or warning letters, fines, import and export restrictions, product recalls or seizures, injunctions, total or partial suspension of production, civil penalties, withdrawals of previously approved marketing applications, recommendations by the FDA or other regulatory authorities against governmental contracts, and/or criminal prosecutions.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we or our collaborators are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We, or any current or future collaborators, cannot assure you that we will receive the approvals necessary to commercialize for sale any of our product candidates, or any product candidate we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from applicable regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. To obtain FDA approval of any product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe and effective for its intended use. This requires significant research, nonclinical studies, and clinical studies. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe and effective for their indicated uses. The FDA has substantial discretion in the approval process and might require us to conduct additional nonclinical and clinical testing, perform post-marketing studies or otherwise limit or impose conditions on any approval we obtain.

The approval process might also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals might: delay commercialization of, and our ability to derive product revenues from, our product candidates; impose costly procedures on us; and diminish any competitive advantages that we might otherwise enjoy.

Even if we comply with all FDA requests, the FDA might ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory approval and commercialize any of our current or future product candidates. In foreign jurisdictions, we are subject to regulatory approval processes and risks similar to those associated with the FDA described above. We cannot assure you that we will receive the approvals necessary to commercialize our product candidates for sale outside the United States.

We and our collaborators may be subject, directly or indirectly, to applicable U.S. federal and state anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations, and health information privacy and security laws, which could expose us or them to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain FDA approval for any of our drug candidates and begin commercializing those drugs in the United States, our operations may be subject to various federal and state fraud and abuse laws, including the federal Anti-Kickback Statute, the federal False Claims Act, and physician payment sunshine laws and regulations. Additionally, we are subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. If we fail to comply with any applicable federal, state or foreign legal requirement, we could be subject to penalties.

Regulators globally are imposing greater monetary fines for privacy violations. The EU GDPR applies to any company established in the EU as well as to those outside the EU if they collect and use personal data in connection with the offering goods or services to individuals in the EU or the monitoring of their behavior. The EU GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and onerous new obligations on services providers. Noncompliance with the EU GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The EU GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the EU GDPR, including as implemented by individual countries. Compliance with the EU GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of developing our products or even prevent us from offering certain products in jurisdictions that we may operate in.

The California Consumer Privacy Act (CCPA) also created new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. While there is currently an exception for protected health information that is subject to HIPAA and clinical study regulations, as currently written, the CCPA may impact our business activities. The uncertainty surrounding the implementation of the CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Violations of these laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal False Claims Act as well as under the false claims laws of several states.

If any of the physicians or other providers or entities with whom we expect to do business with are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

We face the risk of product liability claims and might not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that are inherent in drug development. If the use of one or more of our product candidates or approved drugs, if any, harms people, we might be subject to costly and damaging product liability claims brought against us by clinical study participants, consumers, health care providers, pharmaceutical companies or others selling our products. Our inability to obtain sufficient product liability/clinical study insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop. We cannot predict all of the possible harms or side effects that might result and, therefore, the amount of insurance coverage we maintain might not be adequate to cover all liabilities we might incur. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which might materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our products, our liability could exceed our total assets and our ability to pay. Any successful product liability claims brought against us would decrease our cash and may adversely affect our business, stock price and financial condition.

We might be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research, development and manufacturing activities and/or those of our third-party contractors might involve the controlled use of hazardous materials and chemicals. Although we will strive to have our safety procedures, and those of our contractors, comply with federal, state and local laws and regulations for using, storing, handling and disposing of these materials, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages, and any liability could materially and adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products might require us to incur substantial compliance costs that could materially and adversely affect our business, financial condition and results of operations.

Our employees, independent contractors, consultants, collaborators and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could result in significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct, including failure to:

- comply with applicable regulations of, and provide accurate information to, the FDA or comparable foreign regulatory authorities;
- comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities;
- comply with the FCPA, the U.K. Bribery Act 2010, the PRC Criminal Law, the PRC Anti-unfair Competition Law and other anti-bribery and trade laws;
- report financial information and data accurately; or
- disclose unauthorized activities.

Misconduct could also involve the improper use or misrepresentation of information obtained during clinical studies, creating fraudulent data in our nonclinical studies or clinical studies or illegal misappropriation of product materials, which could result in regulatory sanctions, delays in clinical studies, or serious harm to our reputation.

It is not always possible to identify and deter misconduct. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, 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 harm our business, results of operations, financial condition and cash flows, including through the imposition of significant fines or other sanctions.

Risks Related to Our Intellectual Property

Our business depends on protecting our intellectual property.

If we, our licensors and our collaborators do not obtain protection for our respective intellectual property rights, our competitors might be able to take advantage of our research and development efforts to develop competing drugs. Our success, competitive position and future revenues, if any, depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

We rely upon a combination of patents, trade secret protection and contractual arrangements to protect the intellectual property related to our technologies. We will only be able to protect our products and proprietary information and technology by preventing unauthorized use by third parties to the extent that our patents, trade secrets, and contractual positions allow us to do so. We cannot be certain that we will secure any rights to any issued patents with claims that cover any of our proprietary product candidates and technologies. The patent prosecution process is expensive and time-consuming, and we may be unable to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We could fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection or before our competitors secure patents covering such discoveries. The patent process also is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents.

Composition-of-matter patents relating to the active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products. Such patents provide protection not limited to any one method of use. Method-of-use patents protect the use of a product for the specified method(s) and do not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Formulation patents protect the formulation of a product and do not prevent a competitor from making and marketing a product that has an identical active pharmaceutical ingredient to our product if the product is formulated differently than the patented formulation. We rely on a combination of these and other types of patents to protect our product candidates, and there can be no assurance that our intellectual property will create and sustain the competitive position of our product candidates.

Biotechnology and pharmaceutical product patents involve highly complex legal and scientific questions. Any patent applications that we own or license may fail to result in issued patents. In addition, the U.S. Patent and Trademark Office (USPTO) and patent offices in other jurisdictions often require that patent applications concerning pharmaceutical and/or biotechnology-related inventions are limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. As a result, even if we or our licensors obtain patents, the patents might be substantially narrower than anticipated.

If patents successfully issue from our applications, third parties may challenge their validity or enforceability, which may result in such patents being narrowed, invalidated, or held unenforceable. Even if our patents and patent applications are not challenged by third parties, those patents and patent applications may not prevent others from designing around our claims and may not otherwise adequately protect our product candidates.

Patent and other intellectual property protection is crucial to the success of our business and prospects, and there is a substantial risk that such protections, if obtained, will prove inadequate. The legal systems of certain countries, including China, do not always favor the enforcement of patents, trade secrets, and other intellectual property rights, particularly those relating to pharmaceutical and biotechnology products, which could make it difficult for us to stop infringement of our patents, misappropriation of our trade secrets, or marketing of competing products in violation of our proprietary rights.

Beyond the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how, information, or technology that is not covered by our patents. Although our agreements require all of our employees to assign their inventions to us, and we require all of our employees, consultants, advisors, collaborators, contractors and any third parties who have access to our trade secrets, proprietary know-how and other confidential information and technology to enter into appropriate confidentiality agreements, we cannot be certain that our trade secrets, proprietary know-how and other confidential information and technology will not be subject to unauthorized disclosure or that our competitors will not otherwise gain access to or independently develop substantially equivalent trade secrets, proprietary know-how and other information and technology. If we are unable to prevent unauthorized disclosure of our intellectual property related to our product candidates and technology to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business and operations.

We may incur substantial costs as a result of litigation or other proceedings relating to our patents and other intellectual property rights.

We may in the future be involved in legal or administrative proceedings involving our intellectual property, including infringement of our intellectual property by third parties. These lawsuits or proceedings likely would be expensive, consume time and resources and divert the attention of managerial and scientific personnel, even if we were successful in stopping the infringement of such patents. There is a risk that these proceedings will decide that such patents or other intellectual property rights are not valid and that we do not have the right to stop the other party from using our inventions. There is also the risk that, even if the validity of such patents is upheld, the court or administrative agency will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. If we were not successful in defending our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our products.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Our competitors may have filed, and may in the future file, patent applications covering products and technologies similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights from third parties to issued patents covering such products and technologies. We cannot guarantee that the manufacture, use or marketing of any product candidates that we develop will not infringe third-party patents.

If a patent infringement suit were brought against us, we may be forced to stop or delay developing, manufacturing, or selling potential products that are claimed to infringe a third party's intellectual property, unless that third party grants us rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others to continue development, manufacture or sale of our products. If we are unable to obtain a license or develop or obtain non-infringing technology, or if we fail to defend an infringement action successfully, or if we are found to have infringed a valid patent, we may incur substantial costs and monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates, any of which could harm our business significantly.

The cost of maintaining our patent protection globally is high and requires continuous review and compliance. We may not be able to effectively maintain our intellectual property position throughout the major markets of the world.

The USPTO and foreign patent authorities require maintenance fees, payments and continued compliance with a number of procedural and documentary requirements. Noncompliance may result in abandonment or lapse of patents or patent applications and a partial or complete loss of patent rights in the relevant jurisdiction. Such a loss could reduce royalty payments for lack of patent coverage from our collaboration partners or may result in competition, either of which could have a material adverse effect on our business.

We have made, and will continue to make, certain strategic decisions in balancing the costs and the potential protections afforded by the patent laws of certain countries. As a result, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing products made using our inventions in and into the United States or other countries. Third parties may use our technologies in territories in which we have not obtained patent protection to develop their own products and may infringe our patents in territories which provide inadequate enforcement mechanisms. Such third-party 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. Such competition could materially and adversely affect our business and financial condition.

Intellectual property rights do not address all potential threats to any competitive advantage we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are the same as, or similar to, our current or future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed.
- We or any of our licensors or strategic partners 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 our intellectual property rights.
- The prosecution of our pending patent applications may not result in granted patents.
- Granted patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, because of legal challenges by our competitors.
- Patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product.
- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates.

Risks Related to Our Common Stock

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to bring a claim in a judicial forum they find favorable for disputes with us or our directors, officers or other employees.

Our amended and restated bylaws provide that, with certain limited exceptions, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of fiduciary duty owed by any of our current or former directors, officers or other employees to us or to our stockholders; (3) any action asserting a claim arising pursuant to the Delaware General Corporation Law, or our certificate of incorporation or bylaws (as each may be amended from time to time); or (4) any action asserting a claim governed by the internal affairs doctrine. Alternatively, if such court does not have jurisdiction, the Superior Court of Delaware, or, if such

other court does not have jurisdiction, the United States District Court for the District of Delaware, will be the sole and exclusive forum for such actions and proceedings. The choice of forum provision 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. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse impact on our business. The choice of forum provision in our amended and restated bylaws will not preclude or contract the scope of exclusive federal or concurrent jurisdiction for actions brought under the federal securities laws, including the Exchange Act or the Securities Act, or the respective rules and regulations promulgated thereunder.

The price of our common stock might fluctuate significantly, and you could lose all or part of your investment.

The price of our common stock fluctuates widely. Continued volatility in the market price of our common stock might prevent a stockholder from being able to sell shares of our common stock at or above the price paid for such shares. The trading price of our common stock may continue to be volatile and subject to wide price fluctuations in response to various factors, many of which are beyond our control, such as the progress, results and timing of our clinical and nonclinical studies and other studies involving our product candidates, the success or failure of our product candidates, the receipt or loss of required regulatory approvals for our product candidates, the availability of capital or the other risks discussed in this "Risk Factors" section.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We recognize the critical importance of developing, implementing, and maintaining robust cybersecurity measures to help maintain the security, confidentiality, integrity, and availability of our business systems and confidential information, including personal information and intellectual property. Our cybersecurity program includes systems and processes that are designed to assess, identify and manage material risks from cybersecurity threats and includes: maintenance and monitoring of information security policies aligned with global regulatory controls; user and employee awareness of cyber policies and practices; simulated phishing exercises; information systems configuration management; identity and information asset protection; infrastructure security systems; and cyber threat operations with regular monitoring and threat hunting. This program includes processes to oversee and identify material risks from cybersecurity threats associated with our use of third-party service providers. We also maintain a cyber incident response plan designed to assist us in identifying, responding to and recovering from cybersecurity incidents. We use the findings from these and other processes to help us improve our information security practices, procedures and technologies. We also collaborate with third parties to assess the effectiveness of our cybersecurity program. These include cybersecurity assessors, consultants, and other external cybersecurity experts to assist in the identification, verification, and validation of material risks from cybersecurity threats, as well as to support associated mitigation plans when necessary.

Cybersecurity is integrated into our overall risk management systems, including our annual enterprise risk management, internal controls, business continuity and crisis management, third-party risk management, insurance risk management, and employee compliance processes. Our Cyber Incident Response Team, comprised of our Vice President, General Counsel and Corporate Secretary, our Executive Director, Accounting and Treasury, and our Executive Director, Information Technology, consults with, or provides input to each of these programs to ensure that material risks from cybersecurity threats are appropriately assessed, identified, and managed.

As of the date of this report, there have been no cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our business, strategy, results of operations, or financial condition. For additional description of cybersecurity risks and potential related impacts on the Company, refer to the risk factor captioned "Significant disruptions of information technology systems or breaches of data security, including cybersecurity incidents, could materially and adversely affect our business, results of operations and financial condition" in "Item 1A. Risk Factors."

Governance

While our board of directors has oversight responsibility for risk management generally, the Audit Committee is specifically responsible for overseeing our cybersecurity risk management program to ensure cybersecurity risks are identified, assessed, managed, and monitored. Our Executive Director, Information Technology, who has over 15 years of experience in the cybersecurity field, provides periodic updates to the Audit Committee in this regard, and details our cybersecurity program supported by key performance indicators across the range of cybersecurity functions related to risk management and governance, identity and information asset protection, core security and endpoint security, and cyber threat operations. These updates include descriptions of cybersecurity incidents, including those associated with our third-party service providers. The Audit Committee is responsible for updating our full board of directors on material risks from cybersecurity incidents or threats.

Item 2. Properties

We lease office space for corporate and administrative functions and laboratory space in South San Francisco, California under a sublease that expires in October 2025. Our China subsidiary leases a registrational office in Shanghai, which expires in March 2024.

We believe these leased facilities are adequate for our current needs and that additional space will be available in the future on commercially reasonable terms as needed.

Item 3. Legal Proceedings

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse effect on us because of defense and settlement costs, diversion of management resources and other factors.

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 for Common Stock

Our common stock is traded under the symbol "ASMB" and is quoted on The Nasdaq Global Select Market.

Holders of Record

As of March 22, 2024, there were 47 stockholders of record, which excludes stockholders whose shares were held in nominee or street name by brokers.

Dividend Policy

We have never declared or paid any dividends and do not anticipate paying any dividends on our common stock in the foreseeable future.

Recent Sales of Unregistered Securities

There were no unregistered sales of equity securities in 2023.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Reverse Stock Split

On January 31, 2024, following approval by our stockholders, our board of directors approved the implementation of a reverse stock split of our common stock at a ratio of 1-for-12 (the Reverse Stock Split). The Reverse Stock Split was effective as of February 9, 2024, and our common stock began trading on the Nasdaq Global Select Market on a post-split basis on February 12, 2024. All share and per share amounts of our common stock presented in this Annual Report on Form 10-K have been retroactively adjusted to reflect the Reverse Stock Split.

Item 6. [Reserved]

Item 7. 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 consolidated financial statements and the related notes thereto and other financial information appearing elsewhere in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth in this Form 10-K under "Item 1A. Risk Factors."

Overview

We are a biotechnology company developing innovative therapeutics targeting serious viral diseases with the potential to improve the lives of patients worldwide. Our pipeline includes two helicase-primase inhibitors (HPI) targeting recurrent genital herpes, an orally bioavailable hepatitis delta virus (HDV) entry inhibitor, a clinical stage capsid assembly modulator (CAM) designed to disrupt the replication cycle of hepatitis B virus (HBV) at several key points with the aim of achieving finite treatment and functional cures and research programs focused on the discovery of therapeutics to treat devastating viral diseases, including a non-nucleoside polymerase inhibitor (NNPI) targeting transplant-related herpesviruses and a small molecule interferon-α (IFN-α) receptor (IFNAR) agonist targeting HBV and HDV.

Our Strategy

We have recruited an accomplished leadership team and research and development organization, with a collective team track record of over 15 approved drugs in viral diseases, including hepatitis. Our collaboration with Gilead Sciences, Inc. (Gilead and the Gilead Collaboration) also brings us an industry leading partner with a shared vision of providing differentiated antiviral treatments to patients. For additional information regarding the Gilead Collaboration, see "Collaboration and License Agreements—Gilead Sciences, Inc."

Our Clinical Programs and CTA-Enabling Programs

Recurrent Genital Herpes/HSV-1 and HSV-2

In August 2022, we introduced our first programs outside of hepatitis. Among our new viral targets is recurrent genital herpes. Genital herpes can be caused by either herpes simplex virus type 1 (HSV-1) or herpes simplex virus type 2 (HSV-2). HSV-1 and HSV-2 are acquired by oral or genital contact either during symptomatic or asymptomatic reactivation of the virus. Both viruses replicate in neurons, where they can remain latent for the rest of the patient's life and periodically reactivate, with the virus spreading and replicating in epithelial tissues. Initial infection can be asymptomatic or can be marked by symptoms, including localized pain and painful lesions. Genital herpes recurrence is common and can cause painful genital lesions that can lead to increased transmission and debilitate patients, and symptoms may become more serious with additional episodes. Additional complications include increased risk of HIV infection, as well as associated psychological stress and isolationary thoughts, depression and suicidal ideation. Immunocompromised patients may experience more severe and prolonged symptoms due to increased recurrence rates. While genital herpes can be caused by either HSV-1 or HSV-2, recurrences are more likely to be experienced by patients infected by HSV-2.

There are an estimated 800 million people globally with HSV-2, with an estimated 32 million in the United States and 31 million in France, Germany, Italy and Spain (collectively, the EU4) and the United Kingdom (UK). Only approximately 13% of that population is aware of the infection and have been diagnosed. Awareness and diagnostic rates are impacted due to asymptomatic infections and low screening rates in adults and adolescents due to high false positive rates with current diagnostic assays.

HPIs are antiviral agents in development for HSV-1 and HSV-2, with a clinically validated mechanism of action. HPIs inhibit the HSV helicase-primase complex, which is a unique viral enzyme complex without a human homolog, consisting of helicase, primase and cofactor subunits. Both of these subunits have functions that are essential for viral DNA replication and are conserved across HSV-1 and HSV-2. Unlike nucleoside analogs, these compounds do not require phosphorylation by the HSV thymidine kinase (TK) and ongoing viral replication to become active drugs. As a result, HPIs are active immediately upon reactivation of latent HSV-1 and HSV-2. Furthermore, HPIs are active

against TK-deficient HSV-1 and HSV-2, which is a major mechanism of resistance to nucleoside analogs. In February 2023, we announced the nomination of our first herpesvirus development candidate, ABI-5366 (5366), a long-acting HPI for treatment of recurrent genital herpes, to progress toward CTA-enabling studies. In connection with the Gilead Collaboration, in October 2023, we acquired the rights to ABI-1179 (1179), Gilead's HPI program, which is structurally differentiated from 5366.

Currently, there are three antiviral drugs (all nucleoside analogs) that have been approved in the United States and the EU4/UK for the treatment of genital herpes. No new drugs have been approved to treat genital herpes for more than 25 years. In addition to the approved nucleoside analogs, agents such as local anesthetics or analgesics may be used to alleviate local symptoms of minor pain and discomfort.

Nucleoside analogs can be administered as episodic therapy as individual outbreaks arise or daily as chronic suppressive therapy for those with high post-exposure recurrences. However, these agents are only partially effective at controlling the infection or reducing transmission risk. With current nucleoside analog therapies, only one out of three recurrent genital herpes patients with six or more recurrences per year are able to make it through a year of treatment without a recurrence. There are still high titer (greater than 10^4 HSV-2 DNA copies/mL) shedding episodes under this current standard of care for HSV-2, which can lead to recurrences and transmission of genital herpes.

Based on the limitations of current therapies, we see a path to advancing the treatment paradigm for patients suffering from recurrent genital herpes. To reach that goal, we identified an opportunity to develop a potent, long-acting HPI for recurrent genital herpes, 5366, which has demonstrated a strong nonclinical profile, with low nanomolar potency in vitro against both HSV-1 and HSV-2 clinical isolates, exceptionally low plasma clearance rates in multiple nonclinical models and a projected human half-life of more than seven days. This nonclinical profile has led us to target 5366 for development as a long-acting treatment with the potential to be administered orally or as an injectable.

To date, 5366 has also demonstrated a favorable nonclinical safety profile in Good Laboratory Practice (GLP) toxicology studies, with high safety margins and minimal potential for off-target effects. We currently anticipate the initiation of clinical studies with 5366 by mid-2024.

In addition, we are also advancing 1179, a second, structurally-differentiated HPI with single digit nM potency against HSV-1 and HSV-2 and a nonclinical pharmacokinetics (PK) profile strongly supporting a potential long-acting treatment by oral and injectable administration. GLP toxicology studies are underway and clinical studies are expected to begin by the end of 2024.

Our HBV and HDV Programs

The World Health Organization (WHO) estimates that 296 million people worldwide are chronically infected with HBV as of 2019, and 1.5 million new infections occur each year. HBV is a leading global cause of chronic liver disease and liver transplants, and the WHO estimates that 820,000 people died in 2019 from HBV, mostly due to cirrhosis and hepatocellular carcinoma. Of the 296 million people living with chronic HBV infection, only approximately 30.4 million, or 10.5%, were aware of their infection, and only approximately 6.6 million, or 22%, of those diagnosed received treatment. HBV is a highly prevalent disease that infects more than three times the number of people infected with hepatitis C virus and HIV infections combined, according to the WHO.

HDV is a "satellite virus," because it can only infect people (1) who are already infected with HBV or (2) at the same time as a person is infected with HBV. HDV affects a subset of approximately 12 million HBV infected patients. These patients, which comprise an estimated 4.5% of hepatitis B surface antigen (HBsAg) positive patients, experience a substantially increased disease burden, as they account for 18% of cirrhosis and 20% of hepatocellular carcinoma associated with HBV. HDV is considered the most severe form of hepatitis, as 70% of HDV patients progress to cirrhosis within ten years. While HDV is less prevalent in the United States, it is a significant and serious health problem with inadequate treatment in many parts of Europe, Africa, the Middle East, East Asia and parts of South America. HDV may be significantly underdiagnosed, because there were no HDV-targeted therapies approved until very recently, and the first therapy approved is only approved in the European Union. HDV is known to accelerate disease progression and increase the incidence of liver cirrhosis and liver cancer, which results in higher morbidity and mortality rates than HBV alone.

The current standard of care for chronic HBV infection, nucleos(t)ide analog reverse transcriptase inhibitors (NrtIs), are taken life-long and reduce, but do not eliminate, the virus and result in very low cure rates. No new mechanisms of action (MOA) have been approved for chronic HBV infection in over 25 years. The focus of our HBV program is to improve outcomes and increase the number of patients diagnosed and treated through the development of finite and curative therapies targeting an orthogonal MOA.

The current standard of care treatment for HDV is off-label pegylated IFN-α injected weekly or, in some regions, a large, complex molecule that requires daily injections. There are no approved HDV treatments in the United States, and there is only one approved HDV treatment in Europe. We believe a safe and effective oral small molecule entry inhibitor would be a significant innovation for patients living with HDV, which face a significant and immediate disease burden.

HDV Entry Inhibitor

HDV is a small RNA virus that encodes just two viral proteins and relies on host enzymes as well as the HBsAg from HBV to replicate, which limits the number of HDV-specific antiviral targets. Similar to HBV, HDV utilizes HBsAg to enter hepatocytes by binding the cellular transmembrane protein sodium taurocholate co-transporting peptide (NTCP). NTCP is highly expressed on human hepatocytes, where it serves as one of several proteins involved in the transport of bile acids. The binding of specific small or large molecules to NTCP has been shown to effectively inhibit the interaction of HBsAg with NTCP, which prevents HBV and HDV from infecting hepatocytes.

The inhibition of HBV and HDV infection by molecules that bind NTCP has been demonstrated in vitro, in animal models and clinically. Notably, Bulevirtide, a peptide blocker of NTCP, is the only approved therapy for HDV (approved in the European Union (the EU). The binding of NTCP-targeted HBV/HDV entry inhibitors to NTCP has also been shown to inhibit the transport of certain bile acids into cells, which results in plasma elevations of bile acids; this effect has been well tolerated clinically and may serve as a biomarker of pharmacologically active concentrations of drug in the plasma.

We believe a safe and effective oral small molecule entry inhibitor would be a significant innovation for patients living with HDV and could significantly improve treatment uptake and diagnosis rates, especially when compared with currently available injectable products.

In March 2022, we announced our research program focused on a novel, orally bioavailable small molecule approach to inhibit entry of HBV and HDV by targeting NTCP, and in September 2023, we nominated ABI-6250 (6250). In nonclinical studies, 6250 demonstrated low nanomolar potency against all HBV/HDV genotypes, favorable selectivity for NTCP versus other bile acid transporters, good oral bioavailability and a PK profile in nonclinical species projected to support once-daily oral dosing.

At the European Association for the Study of the Liver's (EASL) International Liver Congress™ in June 2023 and the International HBV Meeting in September 2023, we presented nonclinical characterization of the potencies and properties of our novel class of highly potent, small molecule, orally-bioavailable entry inhibitors. We expect to initiate Phase 1a clinical studies of 6250 by the end of 2024.

Capsid Assembly Modulator

HBV is a DNA virus that infects hepatocytes and establishes a reservoir of covalently closed circular DNA (cccDNA), a unique viral DNA moiety that resides in the nucleus of HBV-infected hepatocytes and is associated with viral persistence and chronic infection. No currently approved oral therapies target cccDNA activity directly, which makes molecules that can modulate cccDNA generation or disrupt its function. As a result, we have worked to discover and develop compounds targeting the core protein, a viral protein involved in numerous aspects of the HBV replication cycle, including the generation of HBV cccDNA.

A benchmark for therapeutic agents aiming to decrease cccDNA levels is the use of several key viral antigens as surrogate biomarkers of active cccDNA. The same biomarkers can be used in both primary human hepatocytes and patients. On this basis, our next-generation CAM, ABI-4334 (4334), has shown nonclinical proof of principle. In a variety of cell culture models, 4334 has demonstrated the ability to reduce production of viral HBV DNA levels as

well as the surrogate markers for cccDNA establishment: HBV e antigen (HBeAg), HBV core-related antigen (HBcrAg) and viral pre-genomic RNA (pgRNA).

As a next-generation CAM, 4334 has been optimized to potently disrupt viral replication (MOA #1) and prevent the establishment and replenishment of new cccDNA (MOA #2). In contrast, while active against MOA #1, first-generation CAMs have not demonstrated adequate potency to sufficiently block cccDNA formation (MOA #2). Further, the current standard of care, NrtIs, impacts the viral life cycle after establishment of cccDNA and can only inhibit production of new viral particles, and it does so incompletely. In mid-2021, we announced the selection of 4334, which was internally discovered, for clinical development. The chemical scaffold of 4334 is novel and distinct from all our prior CAM candidates.

We believe that 4334 has a best-in-class nonclinical profile, with single-digit nanomolar potency against MOA #1 and MOA #2, pan-genotypic activity, an improved resistance profile and a favorable safety profile. Through mechanistic studies presented at multiple conferences, we have demonstrated that 4334 promotes the formation of empty capsids by acceleration of capsid assembly, prevents the formation of cccDNA by disrupting incoming capsids, and prematurely disrupts capsids containing duplex linear DNA, the precursor for integrated HBV DNA.

We expect to initiate Phase 1b clinical studies of 4334 by mid-2024.

Research Programs

Transplant-Associated Herpesviruses

In August 2022, in connection with our announcement of our HPI program, we also introduced our NNPI research program, targeting transplant-associated herpesviruses. In a transplant setting, when patients are experiencing immunosuppression, they are at high risk of uncontrolled viral replication and severe disease brought on by one or more herpesviruses, including cytomegalovirus (CMV), HSV-1, HSV-2 and varicella zoster virus (VZV). Each of these herpesviruses are highly prevalent, as approximately (1) 60% of transplant patients are CMV-positive; (2) 60% of transplant patients are HSV-positive; and (3) 80% of transplant patients are VZV-positive. These viruses establish lifelong latent infections and frequently reactivate in transplant patients due to the use of immunosuppressive drugs following the transplant. These uncontrolled viral infections increase the risk of severe disease and serious complications, including organ rejection, graft loss and death, and impacted approximately 60,000 patients in 2018 in the United States and EU4/UK.

While there are approved antivirals that are administered in a transplant setting. However, currently approved antivirals are not broad spectrum and pose the risk of potentially serious side effects and drug-drug interactions. As a result of these limitations, we identified an opportunity to develop an oral pan-herpes NNPI for these transplant-associated herpesvirus infections, which could greatly advance treatment. Our research team has discovered multiple chemical series of potent, broad-spectrum herpesvirus polymerase inhibitors. In addition, Gilead exclusively licensed us its NNPI program, and we believe the combined effort will speed candidate nomination and enhance our chance of clinical success.

IFNAR Agonist

In July 2022, we introduced our new research program advancing a novel, small molecule IFNAR agonist designed to selectively activate the IFN-α pathway within the liver and offer the convenience of oral dosing. IFN-α is a subcutaneous injectable immune modulatory therapy approved for HBV that has demonstrated functional cure in some HBV patients, but its poor tolerability profile significantly limits its use. Substantial side effects include flu-like symptoms, cytopenias, serious depression and psychiatric effects. In addition, multiple contraindications limit its use, and it requires weekly injections that result in systemic exposure for up to a year.

By focusing exposure on the liver, our investigational IFNAR agonist program aims to engage IFN-α's validated antiviral and immune modulatory mechanisms, retaining the efficacy of IFN-α while reducing systemic exposure to improve tolerability. Lead optimization of multiple IFNAR agonists is in progress.

Collaboration and License Agreements

Gilead Sciences, Inc.

On October 15, 2023, we entered into an Option, License and Collaboration agreement (the Gilead Collaboration Agreement) with Gilead pursuant to which Gilead (1) exclusively licensed to us its HPI program and its NNPI program, while retaining opt-in rights to these programs and (2) has an option to take an exclusive license, on a program-by-program basis, to all of our other current and future pipeline programs. During the 12-year collaboration term (subject to payment of certain extension fees) and for a specified period thereafter, Gilead may exercise its opt-in rights, on a program-by-program basis, at one of two timepoints—completion of a certain Phase 1 study or completion of a certain Phase 2 study for the first product within the program—upon payment of an opt-in fee ranging from $45.0 million to $125.0 million per program depending on the type of program and when the option is exercised. Pursuant to the Gilead Collaboration Agreement, Gilead made an $84.8 million upfront cash payment to us.

If Gilead exercises its opt-in right to any current or future program under the collaboration, we are eligible to receive up to $330.0 million in potential regulatory and commercial milestones on that program, in addition to royalties ranging from the high single-digits to high teens, depending on the clinical stage of the program at the time of the opt-in. Following Gilead's exercise of its option for each of our programs, we may opt in to cover 40% of the research and development costs in the United States and share 40% of the profits and operating loss in the United States for products within the program in lieu of receiving milestones and royalties for that program in the United States, unless we later opt out of the cost/profit share for the program. Prior to Gilead's potential exercise of its opt-in, we will be primarily responsible for all discovery, research and development on both our programs and the two Gilead-contributed programs. Following Gilead's opt-in, Gilead will control the further discovery, research, development, and commercialization on any optioned programs. During the term, Gilead will continue to support the collaboration through extension fees of $75.0 million in each of the third, fifth and seventh years of the collaboration.

The Gilead Collaboration Agreement is subject to termination by either party for the other party's uncured, material breach or insolvency. Subject to certain limitations, we and Gilead both have certain termination for convenience rights, upon sufficient prior written notice, with respect to programs that one party in-licenses from the other (subject to Gilead's option rights), and with respect to Gilead, for programs it has option rights to subject to certain time limitations with respect to existing Company programs). Gilead also has a right to terminate the collaborative activities under the Gilead Collaboration Agreement at certain specified points during the collaboration term. Other customary termination rights are further provided in the Gilead Collaboration Agreement.

We and Gilead also entered into a Common Stock Purchase Agreement and an Investor Rights Agreement (together, the Gilead Equity Agreements), pursuant to which Gilead made an upfront equity investment of $15.2 million by purchasing from us 1,089,472 shares of our common stock at a purchase price of $13.92 per share. If we complete an equity financing (or series of financings) by July 15, 2024 that results in at least $30 million of proceeds to us, then, subject to approval by our stockholders (which was obtained on January 31, 2024), we may require Gilead to purchase additional shares of common stock from us in an amount that results in Gilead owning 29.9% of our then-outstanding voting capital stock. If we do not complete the equity financing or do not require Gilead to purchase the additional shares, Gilead may elect to purchase additional shares of common stock from us in an amount that results in Gilead owning 29.9% of our then-outstanding voting capital stock. The purchase price per share for additional shares purchased by Gilead will be equal to the lesser of (1) a 35% premium to the 30-day volume weighted average price immediately prior to the date of purchase or (2) a 35% premium to the 30-day volume weighted average price immediately prior to delivery by Gilead of notice of the anticipated closing date. The Gilead Equity Agreements also include a three-year standstill provision and two-year lockup provision, each with customary exceptions, and provide Gilead with certain other stock purchase rights and registration rights, as well as the right to designate two directors (or, alternatively, board observers at Gilead's election) to our board of directors. In December 2023, Gilead designated Tomas Cihlar, Ph.D. to serve on our board of directors, and in March 2024, Gilead designated Robert D. Cook II to serve on our board of directors.

BeiGene, Ltd.

In July 2020, we entered into a Collaboration Agreement (the BeiGene Agreement) with BeiGene, Ltd. (BeiGene), granting BeiGene an exclusive, royalty-bearing license to develop and commercialize products containing vebicorvir

(VBR), ABI-H2158 (2158) and ABI-H3733 (3733) in the People's Republic of China, Hong Kong, Taiwan and Macau (the Territory).

Under the BeiGene Agreement, we and BeiGene will collaborate on development activities with respect to the licensed products in accordance with a mutually agreed upon development plan.

Pursuant to the terms of the BeiGene Agreement, BeiGene paid us an upfront amount of $40.0 million, and we were eligible to receive up to approximately $500.0 million in milestone payments, comprised of up to $113.8 million in development and regulatory and $385.0 million in net sales milestone payments. In September 2021, we discontinued development of 2158 following the observation of elevated alanine transaminase (ALT) levels in the Phase 2 clinical study consistent with drug-induced hepatotoxicity, in July 2022, we discontinued VBR because it did not achieve functional cure or finite treatment in our two- and three-drug combination studies and in March 2023, we prioritized 4334 over 3733 based on data from clinical Phase 1 studies of both candidates and chronic toxicology observation for 3733 and announced that we would seek partnering opportunities for the CAMs. In conjunction with the Gilead Collaboration Agreement, we elected to no longer seek partnering or further development of 3733. As of our discontinuation of 3733 development, there are no remaining products in development that have been licensed to BeiGene.

The BeiGene Agreement also contains provisions such as representations and warranties of the parties, terms as to governance of the collaboration, commercialization and regulatory responsibilities of the parties, and manufacturing and supply, including potential adjustments in the event supply costs exceed certain levels. In addition, during the term of the BeiGene Agreement, neither party will commercialize any competing products in the Territory.

BeiGene may terminate the BeiGene Agreement for convenience at any time upon 90 days' advance written notice to us. The BeiGene Agreement also contains customary provisions for termination by either party, including in the event of breach of the BeiGene Agreement, subject to cure.

Indiana University Research and Technology Corporation

In September 2013, we entered into an exclusive license agreement (the IURTC License Agreement) with Indiana University Research and Technology Corporation (IURTC) pursuant to which we acquired, with rights to sublicense, the rights to develop and commercialize products associated with multiple patents and patent applications covering aspects of our HBV program held by IURTC. As part of this agreement, we were obligated to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones. The aggregate amount of all performance milestone payments under the IURTC License Agreement, should all performance milestones through development be met, was $0.8 million, with a portion related to the first performance milestone having been paid. Under the IURTC License Agreement, we were also obligated to pay IURTC royalties based on net sales of the licensed technology ranging from 0.5% to 1.75%. In addition, under the IURTC License Agreement, we paid annual diligence maintenance fees of $0.1 million. Milestone payments received by IURTC were fully creditable against the annual diligence maintenance fee for the year in which the milestone payments were received.

In January 2024, we notified the Indiana University Innovation and Commercialization Office and IURTC that we had decided to terminate the IURTC License Agreement. The termination of the License Agreement will be effective on April 11, 2024, 90 days following the delivery of the termination notice.

Operations

We currently have corporate and administrative offices and research laboratory space in South San Francisco, California as well as a registrational office, but no employees, in China.

Since our inception, we have had no revenue from product sales and have funded our operations principally through debt financings prior to our initial public offering in 2010 and through equity financings and collaborations since then. Our operations to date have been primarily limited to organizing and staffing our company, licensing our product candidates, discovering and developing our product candidates, maintaining and improving our patent portfolio and raising capital.

We have generated significant losses to date, and we expect to continue to generate losses as we develop our product candidates. As of December 31, 2023, we had an accumulated deficit of $785.7 million primarily as a result of research

and development expenses and general and administrative expenses. Because we do not generate revenue from any of our product candidates, our losses will continue as we further develop and seek regulatory approval for, and commercialize, our product candidates. Additionally, we expect our research and development expenses to increase over the coming years as we continue the development of our product candidates. As a result, our operating losses are likely to be substantial over the next several years and thereafter if none of our product candidates are approved or successfully launched. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated 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 financial statements, as well as the reported amounts of revenues and expenses during the reporting periods. Note 2 to the Consolidated Financial Statements describes the significant accounting policies and methods used in the preparation of our consolidated financial statements. We evaluate our estimates and judgments, including those described in greater detail below, on an ongoing basis. We base our estimates on 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.

Revenue Recognition from Collaboration

We analyze our collaboration arrangements to assess whether such arrangements, or transactions between arrangement participants, involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities or are more akin to a vendor-customer relationship. In making this evaluation, we consider whether the activities of the collaboration are considered to be distinct and deemed to be within the scope of the collaborative arrangement accounting standard and those that are more reflective of a vendor-customer relationship and, therefore, within the scope of the revenue with contracts with customers accounting standard. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement.

For arrangements or transactions between arrangement participants determined to be within the scope of the contracts with customers accounting standard, we evaluate the term of the arrangement and recognize revenue when the customer obtains control of promised goods or services in a contract for an amount that reflects the consideration we expect to receive in exchange for those goods or services. For contracts with customers, we apply the following five-step model, each of which requires judgment, in order to determine this amount: (1) identification of the promised goods or services in the contract; (2) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (3) measurement of the transaction price, including the constraint on variable consideration; (4) allocation of the transaction price to the performance obligations; and (5) recognition of revenue when (or as) we satisfy each performance obligation.

We only apply the five-step model to contracts when it is probable we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. As part of the accounting for contracts with customers, we must develop assumptions that require judgment to determine the estimated relative standalone selling price (SSP) of each performance obligation identified in the contract. We then allocate the total transaction price to each performance obligation based on its SSP and recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied.

For recognition of revenue relating to the Gilead Collaboration Agreement, we determined the transaction price and allocated it to a single combined performance obligation, the discovery, research and development services during the collaboration term. We estimated the SSP of extension fees and opt-in rights pursuant to the Gilead Collaboration Agreement using significant estimates, including forecasted revenues and costs, development timelines, discount rates, and probabilities of technical and regulatory success. We concluded none of the options in the contract are performance obligations at the outset of the arrangement as they are contingent upon option exercise, are capable of being distinct from the research and development services and are not offered at a discount to their SSP. We evaluate each performance obligation to determine if it can be satisfied at a point in time or over time, and we measure the services delivered to the customer, which we periodically review based on the progress of the related program. We recognize revenue under the Gilead Collaboration Agreement over time using a cost-based input method. Revenue related to certain performance obligations that are satisfied over time could be materially impacted as a result of changes in the estimated total research effort required to satisfy those obligations. A 10% change in the total estimated

effort required to satisfy the single combined performance obligation related to the Gilead Collaboration Agreement would have changed the related revenue recognized during the year ended December 31, 2023 by as much as $0.5 million. The effect of any change made to an estimated input component and, therefore revenue recognized, would be recorded as a change in estimate. Such changes in estimate could have a material impact on the revenue recognized in a future period. In addition, variable consideration (including regulatory and commercial milestones) must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Research and Development Expense and Accruals

As part of the process of preparing our consolidated financial statements, we are required to estimate certain research and development expenses. This process involves reviewing quotations and contracts, reviewing the terms of our license agreements, communicating with our vendors and applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Such payments are evaluated for current or long-term classification based on when they will be realized or consumed. Examples of estimated amortized or accrued research and development expenses include fees to:

- contract research organizations (CROs) and other service providers in connection with clinical studies;
- contract manufacturing organizations (CMOs) in connection with the production of clinical trial materials; and
- vendors in connection with nonclinical development activities.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows and expense recognition. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In either amortizing or accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the related prepayment or accrual accordingly. Our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting changes in estimates in any particular period. Adjustments to prior period estimates have not been material for the years ended December 31, 2023 and 2022.

We have and may continue to enter into license agreements to access and utilize certain technology. In each case, we evaluate if the license agreement results in the acquisition of an asset or a business. To date, none of our license agreements have been considered to be acquisitions of businesses. For asset acquisitions, the upfront payments to acquire such licenses, as well as any future milestone payments, are immediately recognized as research and development expense when paid, provided there is no alternative future use of the rights in other research and development projects. These license agreements may also include contingent consideration in the form of cash payments to be made for future milestone events. We assess whether such contingent consideration meets the definition of a derivative and to date we have determined that such contingent consideration are not derivatives.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

Collaboration Revenue

The following table summarizes the period-over-period changes in our collaboration revenue (in thousands, except for percentages):

	Year Ended December 31,		$ Change	% Change
	2023	2022	2023 vs. 2022	2023 vs. 2022
Collaboration revenue	$ 7,163	$ —	$ 7,163	100 %

Collaboration revenue for the year ended December 31, 2023 includes the recognition of $4.4 million for services performed under the Gilead Collaboration Agreement entered into in October 2023. Additionally, collaboration revenue includes the recognition of $2.7 million of deferred revenue allocated to 3733 under the BeiGene Agreement upon discontinuing development of 3733, following entering into the Gilead Collaboration, as we prioritize 4334. There was no revenue for the year ended December 31, 2022.

Research and Development Expenses

Research and development expenses consist primarily of employee-related expenses, fees paid to CROs and CMOs, lab supplies and other third-party expenses that support our research and discovery, nonclinical and clinical activities. External costs represent a significant portion of our research and development expenses, which we track on a program-by-program basis following the nomination of a development candidate. We use our employee and infrastructure resources, as well as certain third-party costs, across multiple research and development programs, and we do not specifically allocate these costs to our programs.

The following table summarizes the period-over-period changes in our research and development expenses (in thousands, except for percentages):

	Year Ended December 31,		$ Change	% Change
	2023	2022	2023 vs. 2022	2023 vs. 2022
External expenses:				
Research and discovery	$ 9,741	$ 10,338	$ (597)	(6 %)
3733	3,383	8,165	(4,782)	(59 %)
5366	2,869	—	2,869	100 %
4334	1,947	5,195	(3,248)	(63 %)
VBR	1,755	6,962	(5,207)	(75 %)
6250	421	—	421	100 %
2158	226	2,440	(2,214)	(91 %)
Total external expenses	20,342	33,100	(12,758)	(39 %)
Employee and contractor-related expenses	22,956	31,052	(8,096)	(26 %)
Facility and other expenses	5,602	5,828	(226)	(4 %)
Total research and development expenses	$ 48,900	$ 69,980	$ (21,080)	(30 %)

Research and development expenses were $48.9 million for the year ended December 31, 2023 compared to $70.0 million for the year ended December 31, 2022. The $21.1 million decrease in research and development expenses was primarily driven by decreases in external expenses due to pausing further development of our CAMs as we sought partnering opportunities after the completion of the Phase 1b trial for 3733 and Phase 1a trial for 4334 and our discontinuation of the VBR and 2158 programs. We also experienced decreases in employee and contractor-related expenses of $8.1 million due to the termination of employees as part of the reorganization announced in July 2022. This was partially offset by increases in external expenses generated from the advancement of 5366 and 6250.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs for personnel in executive, finance, accounting, business development, information technology, legal and human resources functions. Other

significant costs include facility costs not otherwise included in research and development expenses, insurance costs, legal fees relating to patents and corporate matters and fees for accounting and consulting services.

The following table summarizes the period-over-period change in our general and administrative expenses (in thousands, except for percentages):

	Year Ended December 31,		$ Change	% Change
	2023	2022	2023 vs. 2022	2023 vs. 2022
General and administrative expenses	$ 22,909	$ 24,134	$ (1,225)	(5%)

General and administrative expenses were $22.9 million for the year ended December 31, 2023, compared to $24.1 million for the year ended December 31, 2022. The decrease of $1.2 million in general and administrative expenses was primarily due to a $2.2 million decrease in salaries and benefits due to a decrease in headcount, largely attributable to the reorganization announced in July 2022. This was partially offset by an increase in legal expenses incurred with entering into the Gilead Collaboration.

Interest and Other Income, Net

Interest income consists of interest earned on our cash and cash equivalents and available-for-sale securities.

The following table summarizes the period-over-period changes in our interest and other income, net (in thousands, except for percentages):

	Year Ended December 31,		$ Change	% Change
	2023	2022	2023 vs. 2022	2023 vs. 2022
Interest and other income, net	$ 3,451	$ 1,022	$ 2,429	238%

Interest and other income, net was $3.5 million for the year ended December 31, 2023, compared to $1.0 million for the year ended December 31, 2022. The increase of $2.4 million was primarily due to more interest income earned on marketable securities caused by multiple interest rate increases in 2023 and a larger portfolio balance after the receipt of $100.0 million upon entering into the Gilead Collaboration in October 2023.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any FDA-approved products to generate product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in October 2005. We have funded our operations through December 31, 2023 principally through equity financings, raising an aggregate of $618.8 million in net proceeds, and strategic collaborations, raising an aggregate of $185.7 million through upfront payments.

Future Funding Requirements

We expect our future operating expenses to increase substantially over the coming years as we continue to advance our candidates into the clinic. We monitor our cash needs and the status of the capital markets on a continuous basis. From time to time, we opportunistically raise capital and have done so numerous times since our initial public offering by issuing equity securities. We expect to continue to raise capital when and as needed and at the time and in the manner most advantageous to us.

We expect our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2025. We have based this estimate on assumptions that may prove to be wrong, and we may utilize our available capital resources sooner than we currently expect. Our contractual obligations include operating lease obligations totaling $2.3 million as of December 31, 2023, of which $1.2 million are short-term. We also enter into contracts in the normal course of business with CROs for clinical trials and CMOs for clinical supply manufacturing and with vendors for nonclinical research studies and other services and products for operating purposes, which generally provide for termination within 30 days of notice.

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

- the scope, progress, results and costs of our ongoing drug discovery, nonclinical development, laboratory testing and clinical studies of our product candidates and any additional clinical studies we may conduct in the future;
- our ability to raise capital despite macroeconomic and geopolitical events impacting financial markets, such as rising inflation, market volatility and risk of recession;
- our ability to realize future potential benefits pursuant to the Gilead Collaboration and maintain the collaboration;
- our ability to manufacture, and to contract with third parties to manufacture, adequate supplies of our product candidates for our clinical studies and any eventual commercialization;
- the costs, timing and outcome of regulatory review of our product candidates; and
- the costs of preparing, filing and prosecuting patent applications in the United States and abroad, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Identifying potential product candidates and conducting nonclinical testing and clinical studies is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will likely be derived from sales of medicines that we do not expect to be commercially available for years, if at all. Accordingly, we will need to continue to rely on additional financings to achieve our business objectives. Adequate additional financings may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to raise additional funds when needed, we may be required to reduce staff, delay, scale back or discontinue our product development and clinical studies or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table summarizes our cash flows for the periods presented (in thousands):

	Year Ended December 31,	
	2023	2022
Operating activities	$ 22,743	$ (84,463)
Investing activities	(69,138)	90,640
Financing activities	13,818	614
Net (decrease) increase in cash and cash equivalents	$ (32,577)	$ 6,791

Operating Activities

Net cash provided by operating activities was $22.7 million for the year ended December 31, 2023. This was primarily due to proceeds of $90.7 million from the upfront payment under the Gilead Collaboration Agreement. This was partially offset by our net loss of $61.2 million, adjusted for $5.1 million recognized for stock-based compensation expense.

Net cash used in operating activities was $84.5 million for the year ended December 31, 2022. This was primarily due to our net loss of $93.1 million, adjusted for $6.6 million recognized for stock-based compensation expense.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2023 was $69.1 million primarily due to purchases of marketable securities, net of maturities.

Net cash provided by investing activities for the year ended December 31, 2022 was $90.6 million. This was due to proceeds of $89.2 million from sales and maturities of marketable securities, net of purchases, and proceeds of $1.5 million received in 2022 from the sale of Microbiome assets in 2021.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023 was $13.8 million resulting from the net proceeds of $9.1 million from the sale of 1,089,472 shares of our common stock in accordance with the Gilead Equity Agreements, $4.5 million from the sale of 261,170 shares of our common stock under our "at-the-market" offering program (the 2020 ATM) and $0.1 million from the issuance of 14,453 shares of common stock under the Assembly Biosciences Amended and Restated 2018 Employee Stock Purchase Plan (2018 ESPP).

Net cash provided by financing activities for the year ended December 31, 2022 was $0.6 million resulting from the net proceeds of $0.3 million from the sale of 25,068 shares of our common stock under the 2020 ATM and $0.3 million from the issuance of 18,819 shares of common stock under the 2018 ESPP.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

(a) Financial Statements

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found on page F-1.

(b) Supplementary Data

Not applicable.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures, as defined in Rule 13a-15(e) promulgated under the Securities and Exchange Act of 1934, as amended (the Exchange Act), that is designed to provide reasonable assurance that information, which is required to be disclosed in our reports filed pursuant to the Exchange Act, is accumulated and communicated to management in a timely manner. At the end of fiscal year ending December 31, 2023, we carried out an evaluation, under the supervision, and with the participation of, our management, including our Chief Executive Officer and President, who serves as our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Chief Executive Officer and President concluded that our disclosure controls and procedures for the fiscal year ending as of December 31, 2023 were effective at reasonable assurance levels.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. A control system, no matter how well designed and operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met. Because of these inherent limitations, management does not expect that our internal controls over financial reporting will prevent all error and all fraud. Under the supervision and with the participation of our management, including our Chief Executive Officer and President, who serves as our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control-Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2023.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting in the fourth quarter of 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Except as set forth below, the information required by this item will be contained in our definitive proxy statement to be filed with the SEC in connection with the Annual Meeting of Stockholders (Proxy Statement) within 120 days after the conclusion of our fiscal year ended December 31, 2023 and is incorporated in this Annual Report on Form 10-K by reference.

Code of Ethics

Our Board has adopted a Code of Ethics for our principal executive officer and all senior financial officers and a Code of Conduct applicable to all of our employees and our directors. Both Codes are available under the "Investors—Corporate Governance" section of our website at www.assemblybio.com. If we make any substantive amendments to, or grant any waivers from, the Code of Ethics for our principal executive officer, principal financial officer, principal accounting officer, controller or persons performing similar functions, or any officer or director, we will disclose the nature of such amendment or waiver on our website or in a Current Report on Form 8-K.

Item 11. Executive Compensation

The information required by this item will be contained in the Proxy Statement and is incorporated into this Annual Report on Form 10-K by reference.

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

Except for the table regarding equity compensation plans, the information required by this item will be contained in the Proxy Statement and is incorporated into this Annual Report on Form 10-K by reference.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth the indicated information as of December 31, 2023 with respect to our equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)		Weighted average exercise price of outstanding options, warrants and rights[1] (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)	
Equity compensation plans approved by security holders	790,667	[2]	$ 47.19	318,868	[3]
Equity compensation plans not approved by security holders	167,426	[4]	$ 132.47	10	[5]
Total	958,093			318,878	

(1) The weighted average exercise price is calculated solely based on the exercise prices of the outstanding stock options and does not reflect the shares that will be issued upon the vesting of outstanding awards of restricted stock units (RSUs), which have no exercise price.

(2) This number includes the following: 19,863 shares subject to stock options granted under the 2010 Equity Incentive Plan (2010 Plan); 211,244 shares subject to outstanding awards granted under the Assembly Biosciences, Inc. Amended and Restated 2014 Stock Incentive Plan (2014 Plan), of which 209,591 were subject

to outstanding stock options and 1,653 were subject to outstanding RSUs; 520,707 shares subject to outstanding awards granted under the Assembly Biosciences, Inc. 2018 Stock Incentive Plan, as amended (2018 Plan), of which 429,157 were subject to outstanding stock options and 91,550 were subject to outstanding RSUs; and 38,853 options assumed by us in connection with our merger with Assembly Pharmaceuticals. This number excludes purchase rights currently accruing under the Assembly Biosciences, Inc. Amended and Restated 2018 Employee Stock Purchase Plan (2018 ESPP).

(3) This number includes: no shares under the 2010 Plan, which has been frozen; 554 shares available for issuance under the 2014 Plan; 264,627 shares available for issuance under the 2018 Plan; and 53,687 shares reserved for issuance under the 2018 ESPP. As of March 22, 2024, assuming each participant purchases the maximum number of shares in the current offering period, no more than 12,896 shares are subject to purchase in the current offering, which ends on May 14, 2024.

(4) This number includes 65,035 shares subject to stock options granted under the 2017 Inducement Award Plan (2017 Inducement Plan); 41,666 shares subject to stock options granted under the 2019 Inducement Award Plan (2019 Inducement Plan); and 60,725 shares subject to outstanding awards granted under the 2020 Inducement Award Plan (2020 Inducement Plan), of which 58,746 were subject to outstanding stock options and 1,979 were subject to outstanding RSUs.

(5) This number includes: 6 shares available for issuance under the 2017 Inducement Plan, no shares under the 2019 Inducement Plan and 4 shares available for issuance under the 2020 Inducement Plan.

Our stockholder-approved equity compensation plans consist of the 2018 Plan, 2014 Plan, the 2010 Plan, stock options assumed in our merger with Assembly Pharmaceuticals and the 2018 ESPP. Effective on June 2, 2016, the 2010 Plan was frozen, and no further grants will be made under the 2010 Plan. Shares that are forfeited under the 2010 Plan on or after June 2, 2016 will become available for issuance under the 2014 Plan. An “Award” under the 2018 Plan, 2014 Plan or 2010 Plan is any right to receive our common stock consisting of non-statutory stock options, incentive stock options, stock appreciation rights, RSUs, or any other stock award.

In May 2018, our stockholders approved the 2018 ESPP and it was amended and restated in May 2021. The 2018 ESPP provides for the purchase by employees of up to an aggregate of 108,333 shares of the Company’s common stock. Eligible employees can purchase shares of our common stock at the end of a predetermined offering period at 85% of the lower of the fair market value at the beginning or end of the offering period.

Our outstanding equity compensation arrangements that have not been approved by our stockholders consist of the 2017 Inducement Plan, the 2019 Inducement Plan and the 2020 Inducement Plan. In April 2017, our board of directors adopted the 2017 Inducement Plan and reserved 66,666 shares of our common stock for issuance under the 2017 Inducement Plan. In August 2019, our board of directors adopted the 2019 Inducement Plan and reserved 41,666 shares of our common stock for issuance under the 2019 Inducement Plan. In March 2020, our board of directors adopted the 2020 Inducement Plan and reserved 66,666 shares of our common stock for issuance under the 2020 Inducement Plan. The only persons eligible to receive grants of awards under the 2017 Inducement Plan, the 2019 Inducement Plan or the 2020 Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq Marketplace Rule 5635(c)(4) and the related guidance under Nasdaq IM 5635-1-that is, generally, a person not previously an employee or director of ours, or following a bona fide period of non-employment, as an inducement material to the individual's entering into employment with us. An “Award” is any right to receive our common stock pursuant to the Inducement Plan, consisting of nonstatutory stock options, stock appreciation rights, restricted stock awards, RSUs, or any other stock award.

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

The information required by this item will be contained in the Proxy Statement and is incorporated into this Annual Report on Form 10-K by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item will be contained in the Proxy Statement and is incorporated into this Annual Report on Form 10-K by reference.

Item 15. Exhibits, Financial Statement Schedules

(a) *Exhibits.* The following exhibits are filed as part of this Annual Report on Form 10-K:

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit No.	Filed Herewith
3.1	Sixth Amended and Restated Certificate of Incorporation dated May 25, 2022.				X
3.2	Certificate of Amendment to Sixth Amended and Restated Certificate of Incorporation of Assembly Biosciences, Inc., dated February 9, 2024.	8-K	02/13/2024	3.1	
3.3	Amended and Restated Bylaws as amended through December 7, 2022.	8-K	12/12/2022	3.1	
4.1	Specimen of Common Stock Certificate.	S-3	12/30/2015	4.1	
4.2	Description of Securities.				X
10.1	Sublease, dated July 26, 2023, by and between Arsenal Biosciences, Inc., as Sublandlord, and Assembly Biosciences, Inc., as Subtenant.	10-Q	11/08/2023	10.1	
10.2‡	Option, License and Collaboration Agreement, dated October 15, 2023, by and between Assembly Biosciences, Inc. and Gilead Sciences, Inc.	8-K	10/17/2023	10.1	
10.3‡	Common Stock Purchase Agreement, dated October 15, 2023, by and between Assembly Biosciences, Inc. and Gilead Sciences, Inc.	8-K	10/17/2023	10.2	
10.4‡	Investor Rights Agreement, dated October 15, 2023, by and between Assembly Biosciences, Inc. and Gilead Sciences, Inc.	8-K	10/17/2023	10.3	
10.5*	Exclusive License Agreement dated September 3, 2013 by and between The Indiana University Research and Technology Corporation and Assembly Pharmaceuticals, Inc.	10-Q	11/17/2014	10.29	
10.6†	Amendment No. 1 to Exclusive License Agreement, by and between Assembly Biosciences, Inc. and the Indiana University Research and Technology Corporation.	10-Q	11/05/2020	10.1	
10.7†	Amendment No. 2 to Exclusive License Agreement, by and between Assembly Biosciences, Inc. and the Indiana University Research and Technology Corporation.	10-Q	11/05/2020	10.2	
10.8†‡	Collaboration Agreement, dated as of July 17, 2020, by and between Assembly Biosciences, Inc. and BeiGene, Ltd.	10-Q	11/05/2020	10.3	
10.9#	Amended and Restated Employment Agreement, dated December 12, 2022, between Assembly Biosciences, Inc. and Jason A. Okazaki.	10-K	03/22/2023	10.7	
10.10#	Employment Agreement, dated May 1, 2020, between Assembly Biosciences, Inc. and William E. Delaney IV, Ph.D., effective as of May 27, 2020.	10-K	02/25/2021	10.12	
10.11#	Employment Agreement, dated November 8, 2023, between Assembly Biosciences, Inc. and Anuj Gaggar, M.D., Ph.D.				X
10.12#	Employment Agreement, dated February 10, 2022, between Assembly Biosciences, Inc. and Nicole S. White, Ph.D., effective as of February 16, 2022.				X
10.13#	2010 Equity Incentive Plan.	S-1/A	10/4/2010	10.14	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit No.	Filed Herewith
10.14#	Assembly Biosciences, Inc. Amended and Restated 2014 Stock Incentive Plan.	8-K	06/06/2016	10.1	
10.15#	Omnibus Amendment to Assembly Biosciences, Inc. Stock Incentive Plans.	10-Q	05/08/2020	10.2	
10.16#	Form of Notice of Stock Option Grant and Stock Option Agreement under the Amended and Restated 2014 Stock Incentive Plan.	10-K	03/22/2023	10.12	
10.17#	Form of Restricted Stock Unit Award Notice and Restricted Stock Unit Award Agreement under the Amended and Restated 2014 Stock Incentive Plan.	10-Q	11/01/2017	10.1	
10.18#	Assembly Biosciences, Inc. 2017 Inducement Award Plan.	10-Q	08/09/2017	10.1	
10.19#	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2017 Inducement Award Plan.	10-Q	08/09/2017	10.2	
10.20#	Form of Restricted Stock Unit Award Notice and Restricted Stock Unit Award Agreement under the 2017 Inducement Award Plan.	10-Q	08/09/2017	10.3	
10.21#	Assembly Biosciences, Inc. 2018 Stock Incentive Plan.	8-K	06/01/2018	10.1	
10.22#	Amendment No. 1 to Assembly Biosciences, Inc. 2018 Stock Incentive Plan.	8-K	05/21/2019	10.2	
10.23#	Amendment No. 3 to Assembly Biosciences, Inc. 2018 Stock Incentive Plan.	8-K	06/16/2020	10.1	
10.24#	Amendment No. 4 to Assembly Biosciences, Inc. 2018 Stock Incentive Plan.	8-K	05/25/2021	10.1	
10.25#	Amendment No. 5 to Assembly Biosciences, Inc. 2018 Stock Incentive Plan.	8-K	05/27/2022	10.1	
10.26#	Amendment No. 6 to Assembly Biosciences, Inc. 2018 Stock Incentive Plan.	8-K	05/30/2023	10.1	
10.27#	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2018 Stock Incentive Plan.	10-K	03/22/2023	10.22	
10.28#	Form of Restricted Stock Unit Award Notice and Restricted Stock Unit Award Agreement under the 2018 Stock Incentive Plan.	8-K	06/01/2018	10.3	
10.29#	Form of Stock Appreciation Right Award Agreement for Non-U.S. Grantees under the Assembly Biosciences, Inc. 2018 Stock Incentive Plan.	8-K	10/12/2018	10.4	
10.30#	Form of Performance-Based Stock Appreciation Right Award Agreement for Non-U.S. Grantees under the Assembly Biosciences, Inc. 2018 Stock Incentive Plan.	10-K	03/11/2022	10.24	
10.31#	Amended and Restated Assembly Biosciences, Inc. 2018 Employee Stock Purchase Plan.	8-K	05/25/2021	10.4	
10.32#	Assembly Biosciences, Inc. 2019 Inducement Award Plan.	10-Q	11/07/2019	10.4	
10.33#	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2019 Inducement Award Plan.	10-Q	11/07/2019	10.5	
10.34#	Assembly Biosciences, Inc. 2020 Inducement Award Plan.	10-Q	05/08/2020	10.3	
10.35#	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2020 Inducement Award Plan.	10-Q	05/08/2020	10.4	
10.36#	Form of Restricted Stock Unit Award Notice and Restricted Stock Unit Award Agreement under the 2020 Inducement Award Plan.	10-Q	05/08/2020	10.5	
10.37	Open Market Sale Agreement by and between Assembly Biosciences, Inc. and Jefferies LLC.	S-3	08/28/2020	1.2	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit No.	Filed Herewith
10.38#	Assembly Biosciences, Inc. 2022 Corporate Bonus Plan.	8-K	02/04/2022	10.1	
21.1	List of Subsidiaries of Assembly Biosciences, Inc.				X
23.1	Consent of Independent Registered Public Accounting Firm.				X
24.1	Power of Attorney (included on signature page).				X
31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1**	Certification of the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
97.1	Clawback Policy.				X
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 Definitions Linkbase Document.				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).				

* Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

† The schedules to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K.

‡ Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

Represents management contracts or compensatory plans or arrangements.

** The certification attached as Exhibit 32.1 that accompanies this Annual Report on Form 10-K is to be deemed furnished and shall not be deemed "filed" with the SEC and is not to be incorporated by reference into any filing of Assembly Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

Item 16. Form 10-K Summary

None.

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ASSEMBLY BIOSCIENCES, INC.

Date: March 28, 2024

By: /s/ Jason A. Okazaki
Name: Jason A. Okazaki
Title: Chief Executive Officer and President

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jason A. Okazaki and John O. Gunderson, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jason A. Okazaki Jason A. Okazaki	Chief Executive Officer, President and Director (Principal Executive Officer and Principal Financial Officer)	March 28, 2024
/s/ Jeanette M. Bjorkquist Jeanette M. Bjorkquist	Executive Director, Accounting and Treasury (Principal Accounting Officer)	March 28, 2024
/s/ William R. Ringo, Jr. William R. Ringo, Jr.	Chairman of the Board	March 28, 2024
/s/ Anthony E. Altig Anthony E. Altig	Director	March 28, 2024
/s/ Tomas Cihlar, Ph.D. Tomas Cihlar, Ph.D.	Director	March 28, 2024
/s/ Gina Consylman Gina Consylman	Director	March 28, 2024
/s/ Robert D. Cook II Robert D. Cook II	Director	March 28, 2024
/s/ Sir Michael Houghton, Ph.D. Sir Michael Houghton, Ph.D.	Director	March 28, 2024
/s/ Lisa R. Johnson-Pratt, M.D. Lisa R. Johnson-Pratt, M.D.	Director	March 28, 2024
/s/ Susan Mahony, Ph.D. Susan Mahony, Ph.D.	Director	March 28, 2024
/s/ John G. McHutchison, A.O., M.D. John G. McHutchison, A.O., M.D.	Director	March 28, 2024

ASSEMBLY BIOSCIENCES, INC.
FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Assembly Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Assembly Biosciences, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, 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.

Critical Audit Matter

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

Collaboration Agreement with Gilead Sciences, Inc.

Description of the Matter	As described in Note 10 to the consolidated financial statements, the Company entered into an Option, License and Collaboration Agreement (the Gilead Collaboration Agreement) and Common Stock Purchase Agreement and an Investor Rights Agreement (the Gilead Equity Agreements) with Gilead Sciences, Inc. during the year ended December 31, 2023. The Company concluded Gilead is a customer and accordingly, the Gilead Collaboration Agreement is within the scope of the revenue from contracts with customers guidance. In determining the appropriate accounting treatment, the Company identified a single combined performance obligation for the discovery, research and development services during the collaboration term, and will recognize revenue over time using a cost-based input method. The Company determined that the total transaction price under the Gilead Collaboration Agreement was $90.7 million, which consisted of an upfront payment of $84.8 million and a $5.9 million premium on the purchase of the Company's common stock that was allocated to the single combined performance obligation under the Gilead Collaboration Agreement. Auditing the Company's revenue recognition for the Gilead Collaboration Agreement is complex and required the Company to apply significant judgment to determine whether any promises or services described in the Gilead Collaboration Agreement meet the criteria of being distinct and capable of being distinct within the context of the contract or represent a material right.
How We Addressed the Matter in Our Audit	To test the conclusion that the various promises under the contract collectively constituted a single combined performance obligation, our audit procedures included, among others, reviewing the Gilead Collaboration Agreement, discussing the potential performance obligations with management, and evaluating whether management's accounting position considered all relevant facts and terms included in the agreement. We further evaluated management's technical analysis and assessed management's conclusions to determine whether they had appropriately considered and applied the guidance and interpretations associated with performance obligations within the scope of the revenue from contracts with customers guidance.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2015.
San Jose, California
March 28, 2024

ASSEMBLY BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands except for share amounts and par value)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 19,841	$ 52,418
Marketable securities	110,406	39,192
Accounts receivable from collaboration	43	944
Prepaid expenses and other current assets	3,497	4,413
Total current assets	133,787	96,967
Property and equipment, net	385	743
Operating lease right-of-use (ROU) assets	2,339	3,195
Other assets	312	889
Total assets	**$ 136,823**	**$ 101,794**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 461	$ 2,493
Accrued research and development expenses	885	3,122
Other accrued expenses	5,744	7,317
Deferred revenue - short-term ($30,915 and $− to a related party)	30,915	—
Operating lease liabilities - short-term	1,220	3,364
Total current liabilities	39,225	16,296
Deferred revenue - long-term ($55,379 and $− to a related party)	55,379	2,733
Operating lease liabilities - long-term	1,122	101
Total liabilities	**95,726**	**19,130**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized as of December 31, 2023 and December 31, 2022; 5,482,752 and 4,074,552 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	5	4
Additional paid-in capital	826,921	807,983
Accumulated other comprehensive loss	(81)	(803)
Accumulated deficit	(785,748)	(724,520)
Total stockholders' equity	41,097	82,664
Total liabilities and stockholders' equity	**$ 136,823**	**$ 101,794**

See Accompanying Notes to the Consolidated Financial Statements

ASSEMBLY BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands except for share and per share amounts)

	Year Ended December 31,	
	2023	**2022**
Collaboration revenue ($4,430 and $− from a related party)	$ 7,163	$ —
Operating expenses		
Research and development	48,900	69,980
General and administrative	22,909	24,134
Total operating expenses	71,809	94,114
Loss from operations	**(64,646)**	**(94,114)**
Other income		
Interest and other income, net	3,451	1,022
Total other income	3,451	1,022
Loss before income taxes	**(61,195)**	**(93,092)**
Income tax expense	(33)	—
Net loss	**$ (61,228)**	**$ (93,092)**
Other comprehensive loss		
Unrealized gain (loss) on marketable securities	722	(384)
Comprehensive loss	**$ (60,506)**	**$ (93,476)**
Net loss per share, basic and diluted	$ (13.38)	$ (23.08)
Weighted average common shares outstanding, basic and diluted	4,577,371	4,034,105

See Accompanying Notes to the Consolidated Financial Statements

ASSEMBLY BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands except for share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2021	**4,010,009**	**$ 4**	**$ 800,772**	**$ (419)**	**$ (631,428)**	**$ 168,929**
Issuance of common stock under at-the-market (ATM) equity offering program, net of issuance costs	25,068	—	325	—	—	325
Issuance of common stock under Employee Stock Purchase Plan (ESPP)	18,819	—	289	—	—	289
Issuance of common stock for settlement of restricted stock units (RSUs)	20,656	—	—	—	—	—
Unrealized loss on marketable debt securities	—	—	—	(384)	—	(384)
Stock-based compensation	—	—	6,597	—	—	6,597
Net loss	—	—	—	—	(93,092)	(93,092)
Balance as of December 31, 2022	**4,074,552**	**$ 4**	**$ 807,983**	**$ (803)**	**$ (724,520)**	**$ 82,664**
Issuance of common stock under ATM equity offering program, net of issuance costs	261,170	—	4,546	—	—	4,546
Issuance of common stock under ESPP	14,453	—	129	—	—	129
Issuance of common stock for settlement of RSUs	43,105	—	—	—	—	—
Issuance of common stock to a related party, net of issuance costs	1,089,472	1	9,142	—	—	9,143
Unrealized gain on marketable debt securities	—	—	—	722	—	722
Stock-based compensation	—	—	5,121	—	—	5,121
Net loss	—	—	—	—	(61,228)	(61,228)
Balance as of December 31, 2023	**5,482,752**	**$ 5**	**$ 826,921**	**$ (81)**	**$ (785,748)**	**$ 41,097**

See Accompanying Notes to the Consolidated Financial Statements

ASSEMBLY BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (61,228)	$ (93,092)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	450	498
Stock-based compensation	5,119	6,593
Net (accretion) amortization of investments in marketable debt securities	(1,585)	155
Non-cash rent expense	3,507	3,505
Loss on disposal of property and equipment	139	—
Changes in operating assets and liabilities:		
Accounts receivable from collaboration	901	(608)
Prepaid expenses and other current assets	916	1,328
Other assets	577	814
Accounts payable	(2,032)	(166)
Accrued research and development expenses	(2,237)	(278)
Other accrued expenses	(1,571)	458
Deferred revenue	83,561	—
Operating lease liabilities	(3,774)	(3,670)
Net cash provided by (used in) operating activities	22,743	(84,463)
Cash flows from investing activities		
Proceeds from maturities of marketable securities	65,015	88,000
Proceeds from sale of property and equipment	24	—
Purchases of property and equipment	(255)	(102)
Purchases of marketable securities	(133,922)	(27,583)
Proceeds from sale of marketable securities	—	28,825
Proceeds from the sale of Microbiome assets	—	1,500
Net cash (used in) provided by investing activities	(69,138)	90,640
Cash flows from financing activities		
Proceeds from the issuance of common stock to a related party, net of issuance costs	9,143	—
Proceeds from the issuance of common stock under ATM equity offering program, net of issuance costs	4,546	325
Proceeds from the issuance of common stock under ESPP	129	289
Net cash provided by financing activities	13,818	614
Net (decrease) increase in cash and cash equivalents	(32,577)	6,791
Cash and cash equivalents at the beginning of the period	52,418	45,627
Cash and cash equivalents at the end of the period	**$ 19,841**	**$ 52,418**
Supplemental non-cash investing and financing activities		
Operating lease liabilities arising from obtaining ROU assets	$ 2,442	$ 171

See Accompanying Notes to the Consolidated Financial Statements

Note 1 - Nature of Business

Overview

Assembly Biosciences, Inc. (together with its subsidiaries, Assembly or the Company), incorporated in Delaware in October 2005, is a biotechnology company developing innovative therapeutics. The Company's pipeline includes two helicase-primase inhibitors (HPI) targeting recurrent genital herpes, an orally bioavailable hepatitis delta virus (HDV) entry inhibitor, a clinical stage capsid assembly inhibitor (CAM) candidate designed to disrupt the replication cycle of hepatitis B virus (HBV) at several key points with the aim of achieving finite treatment and functional cures and research programs focused on the discovery of therapeutics to treat devastating viral diseases, including a non-nucleoside polymerase inhibitor (NNPI) targeting transplant-related herpesviruses and a small molecule interferon-α (IFN-α) receptor (IFNAR) agonist targeting HBV and HDV. The Company operates in one segment and is headquartered in South San Francisco, California.

Liquidity

The Company has not derived any revenue from product sales to date and currently has no approved products. Once a product has been developed, it will need to be approved for sale by the U.S. Food and Drug Administration (FDA) or an applicable foreign regulatory agency. Since inception, the Company’s operations have been financed through the sale of equity securities, the proceeds from the exercise of warrants and stock options, the issuance of debt, and upfront payments related to collaboration agreements. The Company has incurred losses from operations since inception and expects to continue to incur substantial losses for the next several years as it continues its product development efforts. In October 2023, the Company received $100.0 million upon entering into the Option, License and Collaboration Agreement (the Gilead Collaboration Agreement) and the Common Stock Purchase Agreement and an Investor Rights Agreement (collectively, the Gilead Equity Agreements) with Gilead Sciences, Inc. (Gilead). Management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months following the date these consolidated financial statements are issued.

Note 2 - Summary of Significant Accounting Policies and Recent Accounting Pronouncements

Basis of Presentation

These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) and include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

On January 31, 2024, following approval by the Company's stockholders, the Company's board of directors approved the implementation of a reverse stock split at a ratio of 1-for-12 shares of the Company's common stock (the Reverse Stock Split). The Reverse Stock Split was effective as of February 9, 2024 (see Note 15). All share and per share amounts of the Company's common stock presented have been retroactively adjusted to reflect the 1-for-12 Reverse Stock Split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Significant estimates inherent in the preparation of the accompanying consolidated financial statements include estimates for revenue recognition, including the standalone selling price (SSP) for the allocation of transaction price to performance obligations and cost-based inputs, as well as estimates of costs incurred but not yet invoiced for research and development accruals.

The Company's estimates could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible these external factors could have an effect on the Company's estimates and could cause actual results to differ materially from those estimates and assumptions.

Other Risks and Uncertainties

The Company relies on contract research organizations (CROs), including one located in Ukraine that temporarily shut down operations due to Russia's invasion. Though this CRO has resumed operations and the Company continues to utilize this CRO, the Company has reallocated certain work to other global CROs in case the CRO shuts down operations again.

U.S. and global financial markets have experienced volatility and disruption due to other macroeconomic and geopolitical events such as rising inflation, rising interest rates to combat inflation, the risk of a recession, the war between Russia and Ukraine and the Israel-Hamas war. The Company cannot predict at this time to what extent, if at all, it and its employees, CROs, vendors and/or collaborators could potentially be negatively impacted by these events.

Cash and Cash Equivalents

All highly liquid investments, including money market funds, with original maturities of three months or less at the time of purchase are considered to be cash equivalents. All of the Company's cash equivalents have liquid markets and high credit ratings. The Company maintains its cash in bank deposits and other accounts, the balances of which, at times as of and during the years ended December 31, 2023 and 2022, exceeded federally insured limits.

Investments in Marketable Securities

The Company invests its excess cash in debt securities with high credit ratings, including, but not limited to, money market funds classified as cash equivalents, securities issued by the U.S. government and its agencies, corporate debt securities and commercial paper. The Company has designated its investments in marketable securities as available-for-sale and measures these securities at their respective fair values. The Company reviews all available-for-sale securities at each period end to determine if they remain available-for-sale based on their current intent and ability to sell the security if it is required to do so. Marketable securities are classified as short-term or long-term based on the maturity date and their availability to meet current operating requirements. Marketable securities that mature in one year or less from the consolidated balance sheet date are classified as short-term available-for-sale securities, while marketable securities with maturities in one year or beyond one year from the consolidated balance sheet date are classified as long-term.

The Company periodically reviews its marketable securities for declines in fair value below the amortized cost basis to determine whether the impairment, if any, is due to credit-related or other factors. This review includes the credit worthiness of the security issuers, the severity of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not the Company will be required to sell the securities before the recovery of the amortized cost basis. Unrealized gains and losses on available-for-sale securities are reported in other comprehensive loss, and as a component of stockholders' equity until their disposition, with the exception of unrealized losses believed to be related to credit losses which are recognized as an allowance for credit losses on the consolidated balance sheet with the corresponding charge in other income in the period the impairment occurs. Impairment assessments are made at the individual security level each reporting period. The Company elected to exclude accrued interest receivable from the amortized cost basis of its available-for-sale debt securities and to not measure an allowance for credit losses for accrued interest receivable. To date, there have been no credit-related declines in value or other impairments of the Company's investments in marketable securities. Realized gains and losses from the sale of marketable securities, if any, are calculated using the specific-identification method.

Leases

All of the Company's leases are operating leases for facilities and equipment. The Company recognizes a lease asset for its right to use the underlying asset and a lease liability for the corresponding lease obligation. The Company determines whether an arrangement is or contains a lease at contract inception. Operating leases with a duration greater than one year are included in operating lease ROU assets, operating lease liabilities - short-term, and operating lease liabilities - long-term in the Company's consolidated balance sheets. The Company elected

the short-term lease exception policy, permitting it to not apply the recognition requirements to leases with terms of less than one year (short-term leases) for all classes of assets. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date. The incremental borrowing rate represents the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease. The Company considers a lease term to be the noncancelable period that it has the right to use the underlying asset, including any periods where it is reasonably assured the Company will exercise the option to extend the contract. Periods covered by an option to extend are included in the lease term if the lessor controls the exercise of that option.

The operating lease ROU assets also include any lease payments made and exclude lease incentives. Lease expense is recognized on a straight-line basis over the expected lease term. Variable lease expenses are recorded when incurred. The Company has elected not to separate lease and non-lease components for its leased assets and accounts for all lease and non-lease components of its agreements as a single lease component.

Impairment of Long-Lived Assets

The Company monitors the carrying value of long-lived assets, including ROU operating lease assets, for potential impairment and tests the recoverability of such assets whenever events or changes in circumstances indicate the carrying amounts may not be recoverable. If a change in circumstance occurs, the Company performs a test of recoverability by comparing the carrying value of the asset or asset group to its undiscounted expected future cash flows. If cash flows cannot be separately and independently identified for a single asset, the Company will determine whether impairment has occurred for the group of assets for which the Company can identify the projected cash flows. If the carrying values are in excess of undiscounted expected future cash flows, the Company measures any impairment by comparing the fair value of the asset or asset group to its carrying value. There was no impairment of long-lived assets during the years ended December 31, 2023 and 2022.

Property and Equipment, Net

Property and equipment are stated at cost and consist of lab and office equipment and leasehold improvements. The Company records depreciation under the straight-line method over the estimated useful lives of its property and equipment ranging from two to seven years.

Leasehold improvements are amortized over the remaining terms of the respective leases or the estimated useful life of the leasehold improvements, whichever is less. Maintenance and repair costs are expensed as incurred.

Fair Value Measurements

The Company follows accounting guidance on fair value measurements for financial instruments measured on a recurring basis, as well as for certain assets and liabilities that are initially recorded at their estimated fair values. Fair value is defined as the exit price, or the amount that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company uses the following three-level hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs to value its financial instruments:

Level 1: Observable inputs such as unadjusted quoted prices in active markets for identical instruments.

Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the marketplace.

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

Financial instruments 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 assessment of the significance of a particular input to the fair value measurement in its entirety requires the Company to make judgments and consider factors specific to the asset or liability. The use of different assumptions and/or estimation methodologies may have a material effect on estimated fair values. Accordingly, the fair value estimates disclosed or initial amounts recorded may not be indicative of the amount the Company or holders of the instruments could realize in a current market exchange.

The carrying amounts of cash equivalents and marketable securities approximate their fair value based upon quoted market prices. Certain of the Company's financial instruments are not measured at fair value on a recurring basis but are recorded at amounts which approximate their fair value due to their liquid or short-term nature, such as cash, accounts receivable, accounts payable and accrued expenses.

The following tables present the fair value of the Company's financial assets measured at fair value on a recurring basis using the above input categories (in thousands):

	December 31, 2023			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents				
Money market fund	$ 18,982	$ —	$ —	$ 18,982
Total cash equivalents	18,982	—	—	18,982
Short-term marketable securities				
U.S. and foreign corporate debt securities	—	17,633	—	17,633
U.S. treasury securities	—	77,018	—	77,018
U.S. and foreign commercial paper	—	15,755	—	15,755
Total short-term marketable securities	—	110,406	—	110,406
Total assets measured at fair value	$ 18,982	$ 110,406	$ —	$ 129,388

	December 31, 2022			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents				
Money market fund	$ 49,676	$ —	$ —	$ 49,676
Total cash equivalents	49,676	—	—	49,676
Short-term marketable securities				
U.S. and foreign corporate debt securities	—	18,597	—	18,597
U.S. treasury securities	—	11,744	—	11,744
U.S. and foreign commercial paper	—	8,851	—	8,851
Total short-term marketable securities	—	39,192	—	39,192
Total assets measured at fair value	$ 49,676	$ 39,192	$ —	$ 88,868

Money market funds are highly liquid and actively traded marketable securities that generally transact at a stable $1.00 net asset value representing its estimated fair value. The Company estimates the fair value of its U.S. and foreign corporate debt securities, U.S. treasury securities and U.S. and foreign commercial paper by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs.

There have been no transfers between Level 1, Level 2 or Level 3 for any of the periods presented. See Note 4 for further information regarding the carrying value of the Company's investments in marketable securities.

Revenue Recognition and Accounts Receivable from Collaboration

The Company analyzes its collaboration arrangements to assess whether such arrangements, or transactions between arrangement participants, involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities or are more akin to a vendor-customer relationship. In making this evaluation, the Company considers whether the activities of the collaboration are considered to be distinct and deemed to be within the scope of the collaborative arrangement accounting standard and those that are more reflective of a vendor-customer relationship and, therefore, within the scope of the revenue with contracts with customers accounting standard. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement.

For elements of collaboration arrangements that are not accounted for pursuant to the revenue from contracts with customers accounting standard, an appropriate recognition method is determined and applied consistently, generally by analogy to the revenue from contracts with customers accounting standard. Amounts related to transactions with a

counterparty in a collaborative arrangement that is not a customer are presented on a separate line item from revenue recognized from contracts with customers, if any, in the Company's consolidated statements of operations and comprehensive loss.

Under certain collaborative arrangements, the Company has been reimbursed for a portion of its research and development expenses or participates in the cost-sharing of such research and development expenses. Such reimbursements and cost-sharing arrangements are reflected as a reduction of research and development expense in the Company's consolidated statements of operations and comprehensive loss.

For arrangements or transactions between arrangement participants determined to be within the scope of the contracts with customers accounting standard, the Company evaluates the term of the arrangement and recognizes revenue when the customer obtains control of promised goods or services in a contract for an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. For contracts with customers, the Company applies the following five-step model in order to determine this amount: (1) identification of the promised goods or services in the contract; (2) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (3) measurement of the transaction price, including the constraint on variable consideration; (4) allocation of the transaction price to the performance obligations; and (5) recognition of revenue when (or as) the Company satisfies each performance obligation.

The Company has provided standard indemnification and protection of licensed intellectual property for its customers. These provisions are part of assurance the licenses meet the agreements, representations and are not obligations to provide goods or services.

The Company only applies the five-step model to contracts when it is probable the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. As part of the accounting for contracts with customers, the Company must develop assumptions that require judgment to determine the estimated relative SSP of each performance obligation identified in the contract. The Company then allocates the total transaction price to each performance obligation based on the SSP of each performance obligation. The Company recognizes the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied or as it is satisfied as revenue.

Licenses

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, upfront license fees based on the relative value prescribed to the license compared to the total value of the arrangement. The revenue is recognized when the license is transferred to the collaborator and the collaborator is able to use and benefit from the license. For licenses that are not distinct from other obligations identified in the arrangement, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, the Company applies an appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable, upfront license fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Research and Development Services

The promises under the Company's agreements may include research and development services to be performed by the Company on behalf of the counterparty. If these services are determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to these services as revenue over time based on an appropriate measure of progress when the performance by the Company does not create an asset with an alternative use and the Company either has received or has an enforceable right to payment for the performance completed to date. If these services are determined not to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to the combined performance obligation as the related performance obligations are satisfied.

Customer Options

If an arrangement contains customer options, the Company evaluates whether the options are material rights because they allow the customer to acquire additional goods or services for free or at a discount. 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 identification of a material right, and if identified as a material right, the allocation of the transaction price to it, is based on the SSP, which is determined using assumptions regarding estimated costs,

discount rates, post-option development timeline, the probability of technical and regulatory success and the probability the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised or expires. If the options are deemed not to be a material right, they are considered marketing offers which are excluded as performance obligations at the outset of the arrangement.

Development and Regulatory Milestone Payments

Depending on facts and circumstances, the Company may record revenues from certain milestones in a reporting period before the milestone is achieved if the Company concludes achievement of the milestone is probable and recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. The Company records a corresponding contract asset when this conclusion is reached. Milestone payments that have not been included in the transaction price to date are fully constrained. The Company re-evaluates the probability of achievement of such milestones and any related constraint each reporting period. The Company adjusts its estimate of the overall transaction price, including the amount of collaborative revenue that was recorded, if necessary.

Sales-based Milestone and Royalty Payments

The Company's customers may be required to pay the Company sales-based milestone payments or royalties on future sales of commercial products. The Company recognizes revenues related to sales-based milestone and royalty payments upon the later to occur of (i) achievement of the collaborator's underlying sales or (ii) satisfaction of any performance obligation(s) related to these sales, in each case assuming the Company's licensed intellectual property is deemed to be the predominant item to which the sales-based milestones and/or royalties relate.

The Company receives payments from its customers based on billing schedules established in the contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under the arrangement. If the related performance obligation is expected to be satisfied within the next twelve months, these amounts will be classified in current liabilities. The Company recognizes a contract asset relating to its conditional right to consideration that is not subject to a constraint. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

A net contract asset or liability is presented for each contract with a customer. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

At December 31, 2023 and 2022, all accounts receivable from collaboration are deemed collectible.

Contract Liabilities

The following tables present changes in the Company's contract liabilities (in thousands):

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Year Ended December 31, 2023				
Contract liabilities:				
Deferred revenue	$ 2,733	$ 90,724	$ (7,163)	$ 86,294

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Year Ended December 31, 2022				
Contract liabilities:				
Deferred revenue	$ 2,733	$ —	$ —	$ 2,733

	Year Ended December 31,	
	2023	2022
Collaboration revenue recognized in the period from		
Amounts included in deferred revenue at the beginning of the period	$ 2,733	$ —
Performance obligations satisfied in previous period	$ —	$ —

Stock-Based Compensation

The Company measures stock-based compensation to employees, consultants, board members, and non-employees at fair value on the grant date of the award. The fair value of RSUs is determined based on the number of shares granted and the quoted market price of the Company's common stock on the date of grant. If stock-based awards are granted in contemplation of or shortly before a planned release of material nonpublic information, and such information is expected to result in a material increase in the Company's share price, the Company considers whether an adjustment to the observable market price is required when estimating fair values. Compensation cost is recognized as expense on a straight-line basis over the requisite service period of the award. Stock-based awards with graded vesting schedules are recognized using the accelerated attribution method on a straight-line basis over the requisite service period for each separately vesting portion of the award. For awards that have a performance condition, compensation cost is measured based on the fair value of the award on the grant date, the date performance targets are established, and is expensed over the requisite service period for each separately vesting tranche when achievement of the performance condition becomes probable. The Company assesses the probability of the performance conditions being met on a continuous basis. For awards that have a market condition, compensation cost is measured based on the grant-date fair value of the award and is expensed over the derived service period regardless of whether the underlying market condition is met. Forfeitures are recognized when they occur.

The Company estimates the fair value of stock option grants that do not contain market-based vesting conditions using the Black-Scholes option pricing model. The assumptions used in estimating the fair value of these awards, such as expected term, expected dividend yield, volatility and risk-free interest rate, represent management's best estimates and involve inherent uncertainties and the application of management's judgment. The Company uses the Monte-Carlo model to calculate the fair value on the date of grant of awards which contain market-based vesting conditions. This pricing model uses multiple simulations to evaluate the probability of achieving the market condition to calculate the fair value of the awards, which includes the recent market price and volatility of the Company's shares. The Company is also required to make estimates as to the probability of achieving the specific performance conditions. If actual results are not consistent with the Company's assumptions and judgments used in making these estimates, the Company may be required to increase or decrease compensation expense, which could be material to the Company's consolidated results of operations.

Research and Development Expense and Accruals

Research and development costs include personnel-related costs, outside contracted services including clinical study costs, facilities costs, fees paid to consultants, milestone payments prior to FDA approval, license fees prior to FDA approval, professional services, travel costs, dues and subscriptions, depreciation and materials used in clinical trials and research and development and costs incurred under the Company's collaboration agreements. Research and development costs are expensed as incurred unless there is an alternative future use in other research and development projects. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Such payments are evaluated for current or long-term classification based on when they will be realized or consumed.

The Company records expenses related to clinical studies and manufacturing development activities based on its estimates of the services received and efforts expended pursuant to contracts with multiple CROs and manufacturing vendors that conduct and manage these activities on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical study milestones. In amortizing or accruing service fees, the Company estimates the time period over which services will be performed, enrollment of subjects, number of sites activated and the level of effort expended in each period. If the actual timing of the performance of services or the level of effort varies from the Company's estimate, the Company will adjust the accrued or prepaid expense balance accordingly. To date, there have been no material differences from the Company's estimates to the amounts actually incurred.

The Company has entered and may continue to enter into license agreements to access and utilize certain technology. In each case, the Company evaluates if the license agreement results in the acquisition of an asset or a business. To date, none of the Company's license agreements have been considered to be acquisitions of businesses. For asset acquisitions, the upfront payments to acquire such licenses, as well as any future milestone payments, are immediately recognized as research and development expense when paid, provided there is no alternative future use of the rights in other research and development projects. These license agreements may also include contingent consideration in the form of cash payments to be made for future milestone events. The Company assesses whether such contingent consideration meets the definition of a derivative and to date the Company has determined that such contingent consideration are not derivatives.

Restructuring Charges

The Company recognizes restructuring charges related to reorganization plans that have been committed to by management and when liabilities have been incurred. In connection with these activities, the Company records restructuring charges at fair value for (1) contractual employee termination benefits when obligations are associated to services already rendered, rights to such benefits have vested, and payment of benefits is probable and can be reasonably estimated, (2) one-time employee termination benefits when management has committed to a plan of termination, the plan identifies the employees and their expected termination dates, the details of termination benefits are complete, it is unlikely changes to the plan will be made or the plan will be withdrawn and communication to such employees has occurred, and (3) contract termination costs when a contract is terminated before the end of its term.

One-time employee termination benefits are recognized in their entirety when communication has occurred, and future services are not required. If future services are required, the costs are recorded ratably over the remaining period of service. Contract termination costs to be incurred over the remaining contract term without economic benefit are recorded in their entirety when the contract is canceled.

The recognition of restructuring charges requires the Company to make certain judgments and estimates regarding the nature, timing and amount of costs associated with the reorganization plan. To the extent the Company's actual results differ from its estimates and assumptions, the Company may be required to revise the estimates of future accrued restructuring liabilities, requiring the recognition of additional restructuring charges or the reduction of accrued restructuring liabilities already recognized. Such changes to previously estimated amounts may be material to the consolidated financial statements. Changes in the estimates of the restructuring charges are recorded in the period the change is determined. There were no restructuring charges incurred during the year ended December 31, 2023. Changes to previous estimates for restructuring charges were not material during the year ended December 31, 2022.

At the end of each reporting period, the Company evaluates the remaining accrued restructuring balances to ensure that no excess accruals are retained, and the utilization of the provisions are for their intended purpose in accordance with developed restructuring plans.

Variable Interest Entities

The Company reviews agreements it enters into with third party entities, pursuant to which it may have a variable interest in the entity, in order to determine if the entity is a variable interest entity (VIE). If the entity is a VIE, the Company assesses whether or not it is the primary beneficiary of that entity. In determining whether the Company is the primary beneficiary of an entity, the Company applies a qualitative approach that determines whether it has both (1) the power to direct the economically significant activities of the entity and (2) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. If the Company were to determine it is the primary beneficiary of a VIE, the Company would consolidate the statements of operations and financial condition of the VIE into its consolidated financial statements.

The Company's determination about whether it should consolidate such VIEs is made continuously as changes to existing relationships or future transactions may result in a consolidation event.

Income Taxes

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax effects attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carryforwards. 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 establishes a valuation allowance if it is more likely than not the deferred tax assets will not be realized based on an evaluation of objective verifiable evidence. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit.

The Company recognizes and measures uncertain tax positions using a two-step approach set forth in authoritative guidance. The first step is to evaluate the tax position taken or expected to be taken by determining whether the weight of available evidence indicates it is more likely than not the tax position will be sustained in an audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. Significant judgment is required to evaluate uncertain tax positions. The Company evaluates uncertain tax positions on a regular basis. The evaluations are based on a number of factors, including changes in facts and circumstances, changes in tax law, correspondence with tax authorities during the course of the audit, and effective settlement of audit issues. The provision for income taxes includes the effects of any accruals which the Company believes are appropriate. It is the Company's policy to recognize interest and penalties related to income tax matters in income tax expense. No interest or penalties related to uncertain tax positions has been incurred or accrued for any periods presented.

Pursuant to Section 174 of the Internal Revenue Code (Sec. 174), expenses associated with research conducted in the United States are capitalized and amortized over a five-year period. For expenses associated with research outside of the United States, Sec. 174 expenses are capitalized and amortized over a 15-year period.

Net Loss per Share

Basic net loss per common share excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity unless inclusion of such shares would be anti-dilutive. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given the net loss for each period presented.

A reconciliation of the numerators and the denominators of the basic and diluted net loss per common share computations is as follows (in thousands, except for share and per share amounts):

	Year Ended December 31,	
	2023	2022
Numerator:		
Net loss	$ (61,228)	$ (93,092)
Denominator:		
Weighted average common shares and pre-funded warrants outstanding - basic and diluted	4,577,371	4,034,105
Net loss per share - basic and diluted	$ (13.38)	$ (23.08)

Securities excluded from the computation of diluted net loss per share because including them would have been antidilutive are as follows:

	December 31,	
	2023	2022
Options to purchase common stock	862,911	757,418
Common stock subject to purchase under ESPP	13,730	5,971
Unvested RSUs	95,182	141,544
Total	971,823	904,933

Comprehensive Loss

Comprehensive loss is comprised of net loss and adjustments for the change in unrealized gains and losses on investments in available-for-sale marketable securities. The Company displays comprehensive loss and its components in the consolidated statements of operations and comprehensive loss, net of tax effects if any.

Concentrations of Risk

Credit Risk

Financial instruments which potentially subject the Company to credit risk consist primarily of cash, cash equivalents and marketable securities. The Company holds these investments in highly rated financial institutions, and, by policy, limits the amounts of credit exposure to any one financial institution. These amounts at times may exceed federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. The Company has no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Supplier Risk

Certain materials and key components the Company utilizes in its operations are obtained through single suppliers. Since the suppliers of key components and materials must be named in a New Drug Application (NDA) filed with the FDA for a product, significant delays can occur if the qualification of a new supplier is required. If delivery of material from the Company's suppliers were interrupted for any reason, the Company may be unable to supply any of its product candidates for clinical trials.

Customer Risk

During the year ended December 31, 2023, 62% of the Company's collaboration revenue was recognized from a related party, Gilead, under the Gilead Collaboration Agreement (see Note 10). If the collaboration with Gilead does not result in the successful development and commercialization of products or if Gilead terminates the Gilead Collaboration Agreement, the Company may not receive any future payments under the collaboration.

Recently Adopted Accounting Standards

In June 2016, the Financial Accounting Standards Board (the FASB) issued Accounting Standards Update (ASU) No. 2016-13, *Instruments – Credit Losses: Measurement of Credit Losses on Financial Instruments* (ASU 2016-13), which requires expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. ASU 2016-13 limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases. The FASB issued additional amendments to the new guidance related to transition and clarification and deferred the effective date of this standard for all entities except SEC filers that are not smaller reporting companies to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company adopted ASU 2016-13 effective January 1, 2023 on a modified retrospective basis. The adoption of ASU 2016-13 did not have a material impact on the Company's consolidated financial statements.

Accounting Pronouncements to Be Adopted

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which is intended to provide enhanced segment disclosures. The standard will require disclosures about significant segment expenses and other segment items and identifying the Chief Operating Decision Maker and how they use the reported segment profitability measures to assess segment performance and allocate resources. These enhanced disclosures are required for all entities on an interim and annual basis, even if they have only a single reportable segment. The standard is effective for years beginning after December 15, 2023, and interim periods within annual periods beginning after December 15, 2024, with early adoption permitted. The Company is evaluating this standard to determine the impact on the Company's consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The update requires a public business entity to disclose, on an annual basis, a tabular rate reconciliation

using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least 5% of total income tax payments, net of refunds received. Adoption of the ASU allows for either the prospective or retrospective application of the amendment and is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company does not expect ASU 2023-09 to have a material impact on the Company's consolidated financial statements.

Note 3 - Related Party

In October 2023, Gilead purchased 1,089,472 shares of the Company's common stock at a purchase price of $13.92 per share for total proceeds of $15.2 million under the Gilead Equity Agreements (see Note 8). As of December 31, 2023, Gilead held 19.9% of the Company's outstanding voting common stock. In addition to the Gilead Equity Agreements, the Company entered into the Gilead Collaboration Agreement pursuant to which the Company received total proceeds of $84.8 million as an upfront payment (see Note 10). The Company recognized revenue of $4.4 million under the Gilead Collaboration Agreement during the year ended December 31, 2023.

Additionally, Gilead may, at the Company's or Gilead's option, subject to certain conditions, purchase additional shares to increase its holdings up to a maximum of 29.9% of the Company's then-outstanding voting common stock. Under the Investor Rights Agreement, Gilead has the right to designate two directors to the Company's board of directors. The Company appointed each of Gilead's designees to its board of directors in December 2023 and February 2024.

Note 4 - Investments in Marketable Securities

Investments in marketable available-for-sale securities consisted of the following (in thousands):

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Cash equivalents				
Money market fund	$ 18,982	$ —	$ —	$ 18,982
Total cash equivalents	18,982	—	—	18,982
Short-term marketable securities				
U.S. and foreign corporate debt securities	17,595	41	(3)	17,633
U.S. treasury securities	76,891	127	—	77,018
U.S. and foreign commercial paper	15,728	27	—	15,755
Total short-term marketable securities	110,214	195	(3)	110,406
Total cash equivalents and marketable securities	$ 129,196	$ 195	$ (3)	$ 129,388

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Cash equivalents				
Money market fund	$ 49,676	$ —	$ —	$ 49,676
Total cash equivalents	49,676	—	—	49,676
Short-term marketable securities				
U.S. and foreign corporate debt securities	18,903	—	(306)	18,597
U.S. treasury securities	11,968	—	(224)	11,744
U.S. and foreign commercial paper	8,851	—	—	8,851
Total short-term marketable securities	39,722	—	(530)	39,192
Total cash equivalents and marketable securities	$ 89,398	$ —	$ (530)	$ 88,868

Short-term marketable securities held as of December 31, 2023 and 2022 had contractual maturities of less than one year.

There were no realized gains and losses for the years ended December 31, 2023 and 2022. As of December 31, 2023 and 2022, investments which were in an unrealized loss position were not material and generally due to interest rate fluctuations, as opposed to declines in credit quality. The Company determined it has the intent and ability to hold all marketable securities that have been in a continuous loss position until recovery of their amortized cost basis, which may be until maturity. As a result, the Company did not recognize any credit losses related to its investments and all unrealized gains and losses on available-for-sale securities are recorded in accumulated other comprehensive loss on the consolidated balance sheets during the years ended December 31, 2023 and 2022.

Accrued interest receivable was $0.3 million as of December 31, 2023 and 2022 and was recorded in prepaid expenses and other current assets on the consolidated balance sheets. The Company did not write off any accrued interest receivable during the years ended December 31, 2023 and 2022.

See Note 2 for further information regarding the fair value of the Company's investments in marketable securities.

Note 5 - Property and Equipment, Net

Property and equipment, net consists of the following (in thousands):

	December 31,	
	2023	2022
Lab equipment	$ 295	$ 102
Office equipment	238	699
Leasehold improvement	62	1,629
Total property and equipment	595	2,430
Less: Accumulated depreciation	(210)	(1,687)
Property and equipment, net	$ 385	$ 743

Depreciation expense for both the years ended December 31, 2023 and 2022 was $0.5 million and was recorded in both research and development expense and general and administrative expense in the consolidated statements of operations and comprehensive loss.

Note 6 – Other Accrued Expenses

Other accrued expenses consist of the following (in thousands):

	December 31,	
	2023	2022
Accrued expenses:		
Accrued compensation	$ 5,484	$ 6,228
Accrued restructuring charges	—	599
Accrued professional fees and other	260	490
Total accrued expenses	$ 5,744	$ 7,317

Note 7 – Restructurings

In July 2022, the Company and its board of directors approved a strategic plan to align with its refocused pipeline on its next generation capsid assembly modulators (CAMs) and research programs and reduced its workforce by approximately 30%. The Company incurred cumulative restructuring charges of $1.1 million representing all costs to be incurred. These restructuring charges consisted solely of employee severance and related benefits, including $1.0 million in severance payments to executive officers impacted by the restructuring, $0.8 million in one-time termination severance payments and other employee-related costs associated with the restructuring and a reversal of $0.7 million for previously recognized stock-based compensation expense related to forfeited awards based on the Company's policy of recognizing stock-based awards with graded vesting schedules using an accelerated attribution method on a straight-line basis over the requisite service period for each separately vesting portion of the award and to recognize forfeitures when they occur.

There were no restructuring charges incurred during the year ended December 31, 2023. The Company incurred $1.1 million in restructuring charges during the year ended December 31, 2022, $0.9 million of which were included in research and development expenses and $0.2 million in general and administrative expenses.

The following table presents the activity in accrued restructuring charges, included as a component of other accrued expenses on the Company's consolidated balance sheet, during the period (in thousands):

Accrued balance as of December 31, 2021	$	—
Costs incurred		1,879
Reductions for cash payments		(1,280)
Accrued balance as of December 31, 2022	$	599
Reductions for cash payments		(599)
Accrued balance as of December 31, 2023	$	—

Note 8 - Stockholders' Equity

The Company is authorized to issue 5,000,000 shares of preferred stock as of December 31, 2023 and 2022. As of December 31, 2023 and 2022, no shares of preferred stock were issued and outstanding. In May 2022, the Company's stockholders approved the Sixth Amended and Restated Certificate of Incorporation, which increased the authorized number of shares of common stock to 150,000,000. The Company is authorized to issue 150,000,000 shares of common stock as of December 31, 2023 and 2022.

Reverse Stock Split

In February 2024, the Reverse Stock Split became effective. All share and per share amounts of the Company's common stock presented have been retroactively adjusted to reflect the 1-for-12 Reverse Stock Split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital (see Note 15). The Company's authorized shares of common stock remain at 150,000,000 and its authorized shares of preferred stock remain at 5,000,000.

Sale of Common Stock

In August 2020, the Company entered into a sales agreement under which the Company may offer and sell shares of its common stock having an aggregate offering price of up to $100.0 million through "at-the-market" offerings (2020 ATM), pursuant to its shelf registration statement on Form S-3 on file with the SEC. During the year ended December 31, 2023, the Company issued and sold 261,170 shares of common stock under the 2020 ATM, for which the Company received net proceeds of $4.5 million, after deducting commissions, fees and expenses. During the year ended December 31, 2022, the Company issued and sold 25,068 shares of common stock under the 2020 ATM, for which the Company received net proceeds of $0.3 million, after deducting commissions, fees and expenses.

In October 2023, the Company entered into the Gilead Equity Agreements pursuant to which Gilead purchased 1,089,472 shares of the Company's common stock at a purchase price of $13.92 per share for total proceeds of $15.2 million. Of the $15.2 million in proceeds received under the Gilead Equity Agreements, $5.9 million was determined to be a premium on the purchase of the Company's common stock and allocated to the single combined performance obligation under the Gilead Collaboration Agreement (see Note 10). The fair value of Gilead's common stock purchase was $9.3 million and total proceeds from the issuance of common stock under the Gilead Equity Agreements was $9.1 million, net of $0.2 million in issuance costs. Pursuant to the terms of the Gilead Equity Agreements, if the Company completes equity financing by July 15, 2024, which results in at least $30.0 million of proceeds to the Company, then, subject to approval by the Company's stockholders (which was obtained on January 31, 2024), the Company may require Gilead to purchase additional shares of common stock from the Company in an amount that results in Gilead owning 29.9% of the Company's then-outstanding voting capital stock. If the Company does not complete the equity financing or does not require Gilead to purchase the additional shares, Gilead may elect to purchase additional shares of common stock from the Company in an amount that results in Gilead owning 29.9% of the Company's then-outstanding voting capital stock. The purchase price per share for additional shares purchased by Gilead will be equal to the lesser of a 35% premium to the 30-day volume weighted average price immediately prior to the date of purchase or a 35% premium to the 30-day volume weighted average price immediately prior to delivery by Gilead of notice of the anticipated closing date. The Gilead Equity Agreements also include a three-year standstill provision and two-year lockup provision, with customary exceptions, and provide Gilead with certain other stock purchase rights and

registration rights, as well as the right to designate two directors to the Company's board of directors. The Company appointed each of Gilead's designees to its board of directors in December 2023 and February 2024.

Note 9 - Stock-Based Compensation

Equity Incentive Plans

In May 2022, the Company's stockholders approved an amendment to the 2018 Stock Incentive Plan (the 2018 Plan), which increased the aggregate number of shares of common stock reserved under the 2018 Plan to 716,666.

In May 2023, the Company's stockholders approved an amendment to the 2018 Plan, which increased the aggregate number of shares of common stock reserved under the 2018 Plan to 883,333.

As of December 31, 2023, the Company had awards outstanding under the following shareholder approved plans: 2010 Equity Incentive Plan (the 2010 Plan), which has been frozen; the Amended and Restated 2014 Stock Incentive Plan (the 2014 Plan); and the 2018 Plan. Shares of common stock underlying awards that are forfeited under the 2010 Plan on or after June 2, 2016 will become available for issuance under the 2014 Plan. As of December 31, 2023, the Company also had awards outstanding under the Assembly Biosciences, Inc. 2017 Inducement Award Plan, the 2019 Inducement Award Plan, and the Assembly Biosciences, Inc. 2020 Inducement Award Plan. As of December 31, 2023, the Company also had outstanding options it assumed in connection with its merger with Assembly Pharmaceuticals.

The Company issues new shares of common stock to settle options exercised or vested RSUs. The Company also issues new shares of common stock in connection with purchases of shares of common stock by eligible employees under the Assembly Biosciences, Inc. Employee Stock Purchase Plan (the 2018 ESPP).

In February 2024, the Reverse Stock Split became effective. All outstanding stock options and restricted stock units, as well as the Company's equity incentive plans presented have been retroactively adjusted to reflect the 1-for-12 Reverse Stock Split (see Note 15).

Stock Plan Activity

Stock Options

The following table summarizes the stock option activity and related information for 2023:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Total Intrinsic Value (in thousands)
Outstanding as of December 31, 2022	757,418	$ 84.96	7.1	$ —
Granted	190,591	10.68		
Forfeited	(85,098)	81.24		
Outstanding as of December 31, 2023	862,911	$ 69.00	6.7	$ 1
Options vested and exercisable as of December 31, 2023	486,626	$ 104.88	5.1	$ —

The weighted-average grant-date fair value of options granted was $7.68 and $17.76 during the years ended December 31, 2023 and 2022, respectively. There were no options exercised in 2023 or 2022.

RSUs

The following table summarizes RSU activity and related information for 2023:

	Number of RSUs	Weighted Average Fair Value Per RSU at Grant Price
Nonvested as of December 31, 2022	141,544	$ 40.68
Granted	15,936	10.68
Vested	(42,898)	53.28
Forfeited	(19,400)	27.48
Nonvested as of December 31, 2023	95,182	$ 32.64

The total fair value of RSUs vested and settled during 2023 and 2022 was $2.8 million and $2.2 million, respectively. The total intrinsic value of RSUs vested and settled during both 2023 and 2022 was $0.5 million.

In July 2021, the Company granted 26,981 RSUs with performance-based vesting conditions upon the achievement of clinical milestones to the majority of employees, including executive officers. The awards had a grant date fair value of $1.2 million and vest upon performance conditions which were deemed probable of being met as of December 31, 2022. The Company recognized stock-based compensation expense of $0.3 million and $0.7 million for these RSUs during the years ended December 31, 2023 and 2022, respectively.

In March 2022, the Company granted 21,248 RSUs with market-based vesting conditions to members of management, including its executive officers. The awards had a grant date fair value of $0.4 million and are being recognized over the derived service period of 1.5 years and vest upon the achievement of certain market-based conditions which have not been achieved as of December 31, 2023. The Company recognized stock-based compensation expense of $0.1 million and $0.2 million for these RSUs during the years ended December 31, 2023 and 2022, respectively.

In August 2022, the Company granted 43,748 RSUs with performance-based vesting conditions upon the achievement of clinical milestones to its executive officers. The awards had a grant date fair value of $1.1 million. Some of the performance conditions were deemed probable of being met as of December 31, 2022, with the remaining performance conditions deemed probable of being met as of December 31, 2023. The Company recognized stock-based compensation expense of $0.6 million and $0.1 million for these RSUs during the years ended December 31, 2023 and 2022, respectively.

Employee Stock Purchase Plan

The 2018 ESPP provides for the purchase by employees of up to an aggregate of 108,333 shares of the Company's common stock at a discount to the market price. Eligible employees may participate through payroll deductions of up to 15% of such employee's compensation for each pay period subject to annual statutory limits and the 2018 ESPP's limit of 208 shares of common stock per offering.

Eligible employees can purchase the Company's common stock at the end of a predetermined offering period at 85% of the lower of the fair market value at the beginning or end of the offering period. Under the 2018 ESPP, the offering periods end on the last business day occurring on or before May 14 or November 14. The ESPP is compensatory and results in stock-based compensation expense.

In May and November 2023, employees purchased 7,534 and 6,919 shares of common stock, respectively, under the 2018 ESPP. In May and November 2022, employees purchased 11,240 and 7,579 shares of common stock, respectively, under the 2018 ESPP. As of December 31, 2023, 53,687 shares of common stock are available for future sale under the Company's 2018 ESPP. Stock-based compensation expense recorded in connection with the 2018 ESPP was $0.1 million for both the years ended December 31, 2023 and 2022.

Valuation Assumptions

The Company used the Black-Scholes option-pricing model for determining the estimated fair value and stock-based compensation related to stock options and ESPP purchase rights.

A summary of the assumptions used to estimate the fair values of stock options grants for the years presented is as follows:

	Year Ended December 31,	
	2023	2022
Exercise price	$8.64 - $18.36	$18.36 - $29.40
Expected volatility	77.5% - 87.1%	78.5% - 81.7%
Risk-free rate	3.59% - 4.49%	1.41% - 4.15%
Expected term (years)	5.5 - 7.5	5.5 - 7.5
Expected dividend yield	0%	0%

The risk-free interest rate assumption was based on the rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the stock option being valued. The expected dividend yield was zero as the Company currently does not intend to pay dividends in the foreseeable future. The weighted average expected term of options was calculated using the simplified method as prescribed by accounting guidance for stock-based compensation due to the Company's limited history of relevant stock option exercise activity. The expected volatility was calculated based on the Company's historical stock prices.

The fair value of ESPP purchase rights and stock appreciation rights were not material for any period presented.

Stock-Based Compensation Expense

The Company recognized stock-based compensation expense included in the consolidated statement of operations and comprehensive loss for the years presented (in thousands):

	Year Ended December 31,	
	2023	2022
Research and development	$ 2,116	$ 3,024
General and administrative	3,003	3,569
Total stock-based compensation expense	$ 5,119	$ 6,593

As of December 31, 2023, there was $2.9 million of total unrecognized stock-based compensation related to outstanding equity awards which is expected to be recognized over a weighted average remaining amortization period of 1.5 years.

Note 10 - Collaboration Agreements

The following table summarizes the collaboration revenue recognized from the Company's collaboration agreements in the consolidated statement of operations and comprehensive loss for the years presented (in thousands):

	Year Ended December 31,	
	2023	2022
Gilead	$ 4,430	$ —
BeiGene, Ltd. (BeiGene)	2,733	—
Total collaboration revenue	$ 7,163	$ —

Gilead Agreement

In October 2023, the Company entered into the Gilead Collaboration Agreement pursuant to which Gilead will exclusively license to the Company its HPI program and NNPI program, while retaining opt-in rights to these programs and have an option to take an exclusive license, on a program-by-program basis, to all of the Company's other current and future pipeline programs for a 12-year collaboration term. In addition to the Gilead Collaboration Agreement, the Company and Gilead entered into the Gilead Equity Agreements, pursuant to which Gilead purchased 1,089,472 shares of the Company's common stock at a purchase price of $13.92 per share (see Note 8). The Company

received total proceeds of $100.0 million, consisting of $84.8 million as an upfront payment under the Gilead Collaboration Agreement and $15.2 million under the Gilead Equity Agreements.

Pursuant to the terms of the Gilead Collaboration Agreement, during the term and for a specified period thereafter, Gilead may exercise its opt-in rights, on a program-by-program basis, at one of two timepoints – completion of a certain Phase 1 study or completion of a certain Phase 2 study for the first product within the program – and upon payment of an opt-in fee ranging from $45.0 million to $125.0 million per program depending on the type of program and when the option is exercised. If Gilead exercises its opt-in right to any current or future program under the collaboration, the Company is eligible to receive up to $330.0 million in potential regulatory and commercial milestones on that program, in addition to royalties ranging from the high single-digits to high teens, depending on the clinical stage of the program at the time of the opt-in. Following Gilead's exercise of its option for each Company program, the Company may opt in to cover 40% of the research and development costs in the United States and share 40% of the profits and operating loss in the United States for products within the program in lieu of receiving milestones and royalties for that program in the United States, unless the Company later opts out of the cost/profit share for the program. Prior to Gilead's potential exercise of its opt-in, the Company will be primarily responsible for all discovery, research and development on both the Company's programs and the two Gilead-contributed programs. Gilead may conduct certain development activities related to the Gilead Collaboration Agreement which will be reimbursed by the Company. Following Gilead's opt-in, Gilead will control the further discovery, research, development, and commercialization on any optioned programs. During the term, Gilead will continue to support the collaboration through extension fees of $75.0 million in each of the third, fifth and seventh years of the collaboration.

The Gilead Collaboration Agreement is subject to termination by either party for the other party's uncured, material breach or insolvency. Subject to certain limitations, the Company and Gilead both have certain termination for convenience rights, upon sufficient prior written notice, with respect to programs that one party in-licenses from the other (subject to Gilead's option rights), and with respect to Gilead, for programs it has option rights to subject to certain time limitations with respect to existing Company programs). Gilead also has a right to terminate the collaborative activities under the Gilead Collaboration Agreement at certain specified points during the collaboration term.

The Company concluded Gilead is a customer and accordingly, the Gilead Collaboration Agreement is within the scope of the revenue from contracts with customers guidance. The Company identified a single combined performance obligation for the discovery, research and development services during the collaboration term (the R&D Services). The Company concluded the R&D Services are distinct from Gilead's right to obtain an exclusive license to any of the Company's programs as Gilead benefits from the knowledge and expertise gained from the R&D Services and the Company's know-how is not highly specialized in nature. Gilead could perform the R&D Services themselves, particularly considering Gilead contributed its HPI and NNPI programs and Gilead may continue to conduct development activities on programs being developed under the Gilead Collaboration Agreement. None of the options in the contract were deemed to be separate performance obligations as the options did not provide any discounts or other rights which would be considered a material right in the arrangement.

The Company determined the Gilead Collaboration Agreement and Gilead Equity Agreements should be assessed as a single combined transaction because the agreements were negotiated and entered into together, with a single commercial objective. The Company accounted for the agreements based on the fair values of the assets and services exchanged. Of the $15.2 million in proceeds received under the Gilead Equity Agreements, $5.9 million was determined to be a premium on the purchase of the Company's common stock and allocated to the single combined performance obligation under the Gilead Collaboration Agreement. As of the effective date of the Gilead Collaboration Agreement, the total transaction price was determined to be $90.7 million. The value the Company received from the licenses Gilead contributed are not material within the context of the contract and accordingly, the Company made no adjustments to the transaction price for them.

The variable consideration related to the regulatory and commercial milestones has not been included in the transaction price as of December 31, 2023, since Gilead has not opted in to take a license to any of the Company's programs. Any variable consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur pursuant to the Gilead Collaboration Agreement. The Company will reevaluate the transaction price in each reporting period as uncertain events are resolved or other changes in circumstances occur.

The transaction price, including the upfront payment from Gilead, is reflected as collaboration revenue when realized in the Company's consolidated statements of operations. The Company will recognize revenue over time using a cost-based input method, based on internal and external labor cost effort to perform the services, over the initial non-cancellable term of three years since this method best reflects the transfer of services to Gilead. In applying a cost-based input method of revenue recognition, the Company uses actual costs incurred relative to estimated total costs to fulfill each performance obligation. A cost-based input method of revenue recognition requires the Company to make estimates of costs to complete the performance obligation. The cumulative effect of any revisions to estimated costs to complete the performance obligation and associated variable consideration will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

The Company recognized collaboration revenue of $4.4 million during the year ended December 31, 2023. The transaction price for future collaborative activities was recorded as deferred revenue on the consolidated balance sheet as of December 31, 2023, of which $30.9 million was included in deferred revenue - short-term and $55.4 million was included in deferred revenue - long-term. During the year ended December 31, 2023, the Company did not make any payments to Gilead.

Antios Agreement

In July 2021, the Company and Antios Therapeutics, Inc. (Antios) entered into a Clinical Trial Collaboration Agreement (the Antios Agreement) to collaborate on a triple combination therapy using VBR and Antios's active site polymerase inhibitor nucleotide ATI-2173 for the treatment of HBV. Assembly and Antios were individually responsible for the study's manufacturing costs but equally shared the remaining costs of the study. Antios was responsible for conducting the clinical trial with Assembly reimbursing Antios its share of expenses. In May 2022, the Company was notified by Antios that ATI-2173 had been placed on clinical hold by the FDA following submission of a safety report involving a patient who received a triple combination of VBR, ATI-2173 and a nucleos(t)ide analog reverse transcriptase inhibitor (NrtI). Due to the clinical hold, the Company terminated the Antios Agreement effective May 2022.

There were no costs incurred during the year ended December 31, 2023. During the year ended December 31, 2022, the Company incurred $0.4 million in research and development expenses under the Antios Agreement.

Arbutus Biopharma Agreement

In August 2020, the Company and Arbutus Biopharma Corporation (Arbutus Biopharma) entered into a Clinical Trial Collaboration Agreement (Arbutus Biopharma Agreement) to conduct a randomized, multi-center, open-label Phase 2 clinical trial to explore the safety, pharmacokinetics and antiviral activity of the triple combination of VBR, AB-729 and an NrtI compared to the double combinations of VBR with a NrtI and AB-729 with a NrtI. Under the Arbutus Biopharma Agreement, Assembly and Arbutus Biopharma share responsibility for the costs of the trial equally, excluding manufacturing supply which are the burden of each company to supply their respective drugs, VBR and AB-729. Assembly is responsible for conducting this clinical trial with Arbutus Biopharma reimbursing Assembly its share of expenses. In February 2023, Assembly and Arbutus Biopharma decided to terminate the Phase 2 clinical trial early, at the end of the 48-week on-treatment period, and are in the process of closing the study.

The Arbutus Biopharma Agreement is within the scope of the collaborative arrangements guidance as both parties are active participants and are exposed to significant risks and rewards dependent on the success of the collaborative activity. Reimbursements and cost-sharing portions from Arbutus Biopharma are reflected as a reduction of research and development expense when realized in the Company's consolidated statements of operations. The Company recognized a reduction of research and development expense of $1.6 million and $2.7 million under the Arbutus Biopharma Agreement during the years ended December 31, 2023 and 2022, respectively.

BeiGene Agreement

In July 2020, the Company and BeiGene entered into a Collaboration Agreement (the BeiGene Agreement) to develop and commercialize the Company's novel core inhibitor product candidates vebicorvir (VBR), ABI-H2158 (2158) and ABI-H3733 (3733) for chronic HBV infection (the Licensed Product Candidates) in the People's Republic of China, Hong Kong, Taiwan and Macau (the Territory). Under the agreement, the Company and BeiGene are collaborating on certain global clinical studies and both the Company and BeiGene will independently conduct other clinical studies in their own respective territories. During the term of the BeiGene Agreement, neither party will commercialize any competing products in the Territory. In September 2021, the Company discontinued development of 2158 following the observation of elevated alanine transaminase levels in the Phase 2 clinical study consistent with drug-induced hepatotoxicity, and in July 2022, the Company discontinued clinical development of VBR because it did not achieve functional cure or finite treatment in its two- and three-drug combination studies. In conjunction with the Company entering into the Gilead Collaboration Agreement with Gilead in October 2023, the Company discontinued further development and will no longer seek partnering of 3733. As of the Company's discontinuation of 3733 development, there are no remaining products in development which have been licensed to BeiGene.

Pursuant to the terms of the BeiGene Agreement, the Company received an upfront cash payment of $40.0 million from BeiGene for the delivery of exclusive, royalty-bearing licenses to develop and commercialize the Licensed Product Candidates in the Territory, and the Company was eligible to receive up to approximately $500.0 million in cash milestone payments, comprised of up to $113.8 million for development and regulatory milestones and up to $385.0 million in net sales milestones. In addition, the Company was eligible to receive tiered royalties at percentages ranging from the mid-teens to the low thirties of net sales. Due to the discontinuation of development of VBR, 2158 and 3733, the Company is not eligible to receive any development and regulatory milestones or net sales milestones.

The BeiGene Agreement is within the scope of the collaborative arrangements guidance as both parties are active participants and are exposed to significant risks and rewards dependent on the success of commercializing the Licensed Product Candidates in the Territory but that the unit of account related to the delivery of Licensed Product Candidates is within the scope of the contract with customers guidance. The Company identified the following material promises related to the contract with customers unit of account under the BeiGene Agreement: 1) the transfer of the VBR License, 2) the transfer of the 2158 License, and 3) the transfer of the 3733 License. The Company concluded each of these licenses to be functional as they have significant standalone functionality and grant BeiGene the right to use the Company's intellectual property as it exists on the effective date of the license. The Company estimated the SSP of the licenses using an income-based valuation approach for the estimated value a licensor of the compounds would receive considering the stage of the compound's development.

The transaction price at the inception of the agreement was limited to the $40.0 million upfront payment. The variable consideration related to the remaining development and commercialization milestone payments has not been included in the transaction price as these were fully constrained as of December 31, 2023 and 2022. Following the discontinuation of development and decision to no longer seek partnering of 3733, the obligation related to the technology transfer associated with the license of 3733 was considered to be complete. Accordingly, the Company recognized $2.7 million as collaboration revenue for the amount allocated to 3733 during the year ended December 31, 2023. No revenue was recognized during the year ended December 31, 2022. As of December 31, 2023 and 2022, there were no remaining performance obligations under the BeiGene Agreement. The transaction price allocated to 3733 of $2.7 million was recorded as a long-term deferred revenue contract liability on the consolidated balance sheet as of December 31, 2022. During the years ended December 31, 2023 and 2022, the Company did not recognize any increase or reduction of research and development expense under the BeiGene Agreement.

The Company incurred $3.5 million in incremental costs of obtaining the BeiGene Agreement. These contract costs have been capitalized and are being recognized consistent with the pattern of recognition of revenue associated with the Licensed Product Candidates. As of December 31, 2023, no unamortized contract costs remained. As of December 31, 2022, the remaining unamortized contract costs were $0.2 million and were included in other assets on the consolidated balance sheet.

Note 11 – Strategic License Agreements

HBV Research Agreement with Indiana University

Since September 2013, the Company has been party to an exclusive License Agreement dated September 3, 2013 with Indiana University Research and Technology Corporation (IURTC) from whom it has licensed aspects of the Company's HBV program held by IURTC. The license agreement requires the Company to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones. The aggregate amount of all performance milestone payments under the IURTC license agreement, should all milestones through development be met, is $0.8 million, with a portion related to the first performance milestone having been paid. The Company is obligated to pay IURTC royalty payments based on net sales of the licensed technology as well as a portion of any sublicensing revenue Assembly receives. The Company is also required to pay diligence maintenance fees each year to the extent that the royalty, sublicensing, and milestone payments to IURTC are less than such fees for that year. In February 2024, following its decision to discontinue further development or partnering for 3733, the Company terminated the IURTC license agreement, which will become effective April 2024. The Company paid IURTC $0.1 million in diligence maintenance fees during both the years ended December 31, 2023 and 2022, which are included in research and development expenses in the consolidated statements of operations and comprehensive loss.

Door Pharma Agreement

In November 2020, the Company and Door Pharmaceuticals, LLC (Door Pharma) entered into an exclusive, two-year Collaboration Agreement and Sublicense Agreement (collectively, the Door Pharma Agreement) focused on the development of a novel class of HBV inhibitors. The Company terminated the Door Pharma Agreement in May 2022, which became effective September 2022, to focus its resources on its other internal HBV programs and its programs targeting other viruses. Under the terms of the Door Pharma Agreement, the Company was obligated to continue to reimburse Door Pharma for certain research and development costs through September 2022 following which such reimbursements ceased.

Under the consolidation accounting standard, the Company determined Door Pharma was a VIE. The Company did not have the power to direct the activities that most significantly affected the economic performance of Door Pharma and as such the Company was not the primary beneficiary and consolidation was not required prior to the termination of the agreement in May 2022.

The Company did not incur any research and development funding during the year ended December 31, 2023. The Company incurred research and development funding of $1.6 million during the year ended December 31, 2022.

Microbiome Purchase Agreement

In December 2021, the Company entered into an asset purchase agreement (the Microbiome Purchase Agreement) with a third party pursuant to which the Company sold know-how, patents, materials and regulatory filings for the Company's Microbiome program. The sale included ABI-M201 (M201), which had been the Company's lead candidate in its Microbiome program. As consideration for the sale, the Company was entitled to receive $3.0 million, of which $1.5 million was received in 2021 and the remaining $1.5 million was received in 2022. The Company is also entitled to receive a $10.0 million milestone payment upon the achievement of a regulatory approval milestone as defined in the purchase agreement. The variable consideration relating to the $10.0 million milestone has not been included in the transaction price as it was fully constrained as of December 31, 2023 and 2022. As part of the Company's evaluation of the development milestone constraint, it determined the achievement of the milestone is contingent upon success in future clinical studies and regulatory approvals which are not within its control and uncertain at this stage.

Note 12 - Income Taxes

Income tax benefit is as follows (in thousands):

	December 31,	
	2023	2022
Current:		
Federal	$ 33	$ —
State	—	—
Foreign	—	—
	33	—
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
	—	—
Income tax expense	$ 33	$ —

The effective tax rate of the Company's provision for income taxes differs from the federal statutory rate as follows:

	As of December 31,	
	2023	2022
Statutory federal income tax rate	21.0%	21.0%
State taxes, net of federal tax benefit	7.7	8.3
Research and development tax credits	4.4	3.3
Return to provision adjustments	0.3	—
Uncertain tax positions	(0.9)	(0.7)
Stock-based compensation	(1.7)	(2.9)
Other	(0.5)	(0.2)
Change in valuation allowance	(30.4)	(28.8)
Income taxes provision (benefit)	-0.1%	0.0%

Significant components of the Company’s deferred taxes are as follows (in thousands):

	As of December 31,	
	2023	2022
Deferred tax assets:		
Federal and state-operating loss carryforwards	$ 148,119	$ 144,165
Stock-based compensation	9,948	9,919
Capitalized research expense	28,578	15,004
Operating lease liabilities	594	880
Research and development credits	15,816	13,471
Other	19	1,372
Total deferred tax assets	203,074	184,811
Valuation allowance	(202,428)	(184,000)
Deferred tax asset, net of valuation allowance	$ 646	$ 811
Deferred tax liabilities:		
Operating lease right-of-use assets	$ (593)	$ (811)
Other	(53)	—
Total deferred tax liabilities	(646)	(811)
Net deferred tax liability	$ —	$ —

The Company maintains a valuation allowance on deferred tax assets due to the uncertainty regarding the ability to utilize these deferred tax assets in the future. The valuation allowance increased by $18.4 million and $26.9 million

for the years ended December 31, 2023 and 2022, respectively, primarily due to an increase in the Company's federal and state-operating loss carryforwards.

Net operating loss and tax credit carryforwards as of December 31, 2023 are as follows (in thousands):

	Amount	Expiration Years
Net operating losses, federal (post December 31, 2017)	$ 401,038	Indefinite
Net operating losses, federal (pre January 1, 2018)	123,552	2027 - 2037
Net operating loss, state (Indefinite)	880	Indefinite
Net operating loss, state (Definite)	592,044	2031 - 2041
Research and development tax credits, federal	15,203	2028 - 2041
Research and development tax credits, state	6,108	Indefinite

Pursuant to Internal Revenue Code (IRC), Sections 382 and 383, use of the Company's U.S. federal and state net operating loss and research and development income tax credit carryforwards may be limited in the event of a cumulative change in ownership of more than 50.0% within a three-year period. The Company has performed an ownership change study through December 31, 2022 and has determined a "change in ownership" as defined by IRC Section 382 and the rules and regulations promulgated thereunder, did occur in December 2010, January 2013 and October 2014. The Company has adjusted its net operating loss carryovers to appropriately reflect any attributes which will expire due to the limitation. The Company has not completed any additional analysis for IRC Sections 382 and 383 and there is a risk additional changes in ownership could have occurred since December 31, 2022. If a change in ownership were to have occurred, additional net operating loss and tax credit carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

The following table summarizes activity related to the Company's gross unrecognized tax benefits (in thousands):

	As of December 31,	
	2023	2022
Balances as of beginning of year	$ 3,873	$ 3,237
Increases related to prior year tax positions	47	—
Decreases related to prior year tax positions	—	(36)
Increases related to current year tax positions	575	672
Balances as of end of year	$ 4,495	$ 3,873

The unrecognized tax benefits, if recognized, would not have an impact on the Company's effective tax rate assuming the Company continues to maintain a full valuation allowance position. Based on the prior year's operations and experience, the Company does not expect a significant change to its unrecognized tax benefits over the next twelve months. The unrecognized tax benefits may increase or change during the next year for unexpected or unusual items that arise in the ordinary course of business. In subsequent periods, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

The Company files income tax returns in the U.S. federal, California and other state and foreign jurisdictions and is not currently under examination by federal, state, or local taxing authorities for any open tax years. Due to net operating loss carryforwards, all years effectively remain open for income tax examination by tax authorities in the U.S. and states in which the Company files tax returns.

Note 13 - Leases

Operating Leases

In August 2023, the Company entered into a sublease agreement for office and laboratory space in South San Francisco, California to serve as the Company's new corporate headquarters. The sublease contains scheduled annual rent increases over the lease term and expires in October 2025. The Company has the option to extend the sublease through September 30, 2029. The option to extend the Company's corporate headquarters sublease through 2029 is not included in the Company's ROU assets or lease liabilities. The Company's previous corporate headquarters sub-sublease in South San Francisco, California expired in December 2023. The Company also leased office space in Carmel, Indiana under a lease agreement, which expired in August 2023. In February 2021, the Company subleased substantially all of the office space under lease in Carmel, Indiana for the remainder of its term. The Company's China subsidiary leases a registrational office in Shanghai, which expires in March 2024. The Company's registrational office in Beijing, which was month-to-month, ended in 2023. The Company also leases certain laboratory equipment accounted for as operating leases expiring at various dates, with the final lease expiring in 2025.

When the Company cannot determine the implicit rate in its leasing arrangements, the Company uses its incremental borrowing rate as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease within a particular currency environment.

At December 31, 2023, the Company had operating lease liabilities of $2.3 million and ROU assets of $2.3 million.

The following summarizes quantitative information about the Company's operating leases (in thousands):

	Year Ended December 31,	
	2023	2022
Lease cost		
Operating lease cost	$ 3,507	$ 3,505
Short-term lease cost	12	23
Variable lease cost	1,504	1,573
Sublease income	(102)	(153)
Total lease cost, net	$ 4,921	$ 4,948

As of December 31, 2023, the weighted-average remaining lease term for operating leases was 2.5 years and the weighted-average discount rate for operating leases was 10.0%.

As of December 31, 2023, the maturities of the Company's operating lease liabilities were as follows (in thousands):

2024	$ 1,400
2025	1,174
Total	2,574
Less: present value discount	(232)
Operating lease liabilities	$ 2,342

Note 14 - Employee Benefit Plan

In January 2018, the Company established a defined contribution 401(k) plan (the Plan) for all employees who are at least 21 years of age. Employees are eligible to participate in the Plan upon commencement of employment. Under the terms of the Plan, employees may make voluntary contributions as a percentage of compensation. The Plan also permits the Company to make discretionary matching contributions. During the years ended December 31, 2023 and 2022, the Company made discretionary matching contributions of $0.7 million and $0.8 million, respectively.

Note 15 - Subsequent Event

Reverse Stock Split

In September 2023, the Company received a letter from the Listing Qualifications Department of the Nasdaq Stock Market notifying the Company, as the bid price for its common stock had closed below $1.00 per share for the last 30 consecutive business days, it was not in compliance with Nasdaq Listing Rule 5450(a)(1), which is the minimum bid price requirement for continued listing on the Nasdaq Global Select Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided a 180-calendar day period, or until March 25, 2024, to regain compliance with the minimum bid price requirement. The continued listing standard would be met once the closing bid price of the Company's common stock was at least $1.00 per share for a minimum of ten consecutive business days during the 180-calendar day period. In January 2024, the Company's stockholders approved a reverse stock split of its common stock at a range of ratios between 1-for-7 to 1-for-17, and the Company's board of directors approved the implementation of the Reverse Stock Split at a ratio of 1-for-12. The Reverse Stock Split was effective as of February 9, 2024 and the Company regained compliance with the minimum bid price requirement in February 2024.

As of the effective time of the Reverse Stock Split, every 12 issued and outstanding shares of the Company's common stock was automatically reclassified into one issued and outstanding share of the Company's common stock. This reduced the number of shares outstanding from 65.8 million shares to 5.5 million shares. The Reverse Stock Split does not affect the number of authorized shares of common stock or the par value of the common stock. No fractional shares of common stock were issued in connection with the Reverse Stock Split and all fractional shares were rounded down to the nearest whole share with respect to outstanding shares of common stock. Any holders of common stock who would have otherwise received a fractional share of common stock pursuant to the Reverse Stock Split, received cash in lieu of the fractional share. All share and per share amounts of the Company's common stock presented have been retroactively adjusted to reflect the 1-for-12 Reverse Stock Split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital.

Exhibit 3.1

SIXTH AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
ASSEMBLY BIOSCIENCES, INC.

(Pursuant to Sections 242 and 245 of the General Corporation Law of the State of Delaware)

Assembly Biosciences, Inc., a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "DGCL"), certifies that:

A. The name of the corporation is "Assembly Biosciences, Inc." (the "Corporation").

B. The Corporation's original Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on October 7, 2005, under the name South Island Biosciences, Inc., an Amended and Restated Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on October 24, 2005, a Second Amended and Restated Certificate of Incorporation, which included a provision to change the Corporation's name to Ventrus Biosciences, Inc., was filed with the Secretary of State of the State of Delaware on April 5, 2007, a Third Amended and Restated Certificate of Incorporation was filed with the Secretary of the State of Delaware on November 10, 2010 (the "Third Amended and Restated Certificate of Incorporation") and a Certificate of Amendment of the Third Amended and Restated Certificate of Incorporation was filed with the Secretary of State of Delaware on July 10, 2014, which included a provision to change the Corporation's name to Assembly Biosciences, Inc., a Fourth Amended and Restated Certificate of Incorporation was filed with the Secretary of the State of Delaware on May 31, 2018, a Fifth Amended and Restated Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on June 12, 2020 (the "Fifth Amended and Restated Certificate of Incorporation").

C. This Sixth Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") was duly adopted in accordance with Sections 242 and 245 of the DGCL, and hereby amends and restates in its entirety the Fifth Amended and Restated Certificate of Incorporation as follows.

ARTICLE I

The name of the corporation is "Assembly Biosciences, Inc." (the "Corporation").

ARTICLE II

The registered office of the Corporation in the State of Delaware is 251 Little Falls Drive, in the City of Wilmington, County of New Castle 19808. The name of the registered agent of the Corporation at such address is Corporation Service Company.

ARTICLE III

The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the DGCL.

ARTICLE IV

The total number of shares that the Corporation shall have authority to issue, is 155,000,000 (one hundred fifty-five million), consisting of (i) 150,000,000 (one hundred fifty million) shares of common stock, $0.001 par value per share, and (ii) 5,000,000 (five million) shares of preferred stock, $0.001 par value per share.

The board of directors is authorized to issue the preferred stock, subject to limitations prescribed by law and the provisions of this Certificate of Incorporation, as shares of preferred stock in one or more series, and is authorized, by filing a certificate of designation pursuant to the applicable law of the State of Delaware, to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences and rights of the shares of each such series and qualifications, limitations or restrictions thereof. The authority of the board of directors with respect to each series shall include, but not be limited to, determination of the following:

(i) the number of shares constituting that series and the distinctive designation of that series;

(ii) the dividend rate, if any, on the shares of that series, whether dividends shall be cumulative, and, if so, from which date or dates, and the relative rights of priority, if any, of payment of dividends on shares of that series;

(iii) whether that series shall have voting rights or powers, in addition to the voting rights and powers provided by law, and, if so, the terms of such rights;

(iv) whether that series shall have conversion rights, and, if so, the terms and conditions of such conversion, including provisions for adjustment of the conversion rate in such events as the board of directors shall determine;

(v) whether or not the shares of that series shall be redeemable, and, if so, the terms and conditions of such redemption, including the dates or dates upon or after which they shall be redeemable, and the amount per share payable in case of redemption, which amount may vary under different conditions and at different redemption dates;

(vi) whether that series shall have a sinking fund for the redemption or purchase of shares of that series, and, if so, the terms and amounts of such sinking fund;

(vii) the rights of the shares of that series in the event of voluntary or involuntary liquidation, dissolution or winding up of the Corporation, and the relative rights of priority, if any, of payment of shares of that series; and

(viii) any other rights, preferences and limitations of that series.

The board of directors, within the limits and restrictions stated in any resolution or resolutions of the board of directors originally fixing the number of shares constituting any series, may increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series subsequent to the issue of shares of that series.

ARTICLE V

Subject to all the rights, powers and preferences of the preferred stock and except as otherwise required by law or provided in this Certificate of Incorporation (including in any certificate of designations of any series of preferred stock):

(a) the holders of the common stock shall have the exclusive right to vote for the election of directors of the Corporation and on all other matters requiring stockholder action, each outstanding share entitling the holder thereof to one vote on each matter properly submitted to the stockholders of the Corporation for their vote;

(b) dividends may be declared and paid or set apart for payment upon the common stock out of any assets or funds of the Corporation legally available for the payment of dividends, but only when and as declared by the board of directors or any authorized committee thereof; and

(c) upon the voluntary or involuntary liquidation, dissolution or winding up of the Corporation, the net assets of the Corporation shall be distributed pro rata to the holders of the common stock.

ARTICLE VI

Any action required or permitted to be taken by the stockholders of the Corporation must be effected at a duly called annual or special meeting of the stockholders of the Corporation and may not be effected by any consent in writing by such stockholders.

ARTICLE VII

Except as otherwise required by statute and subject to the rights, if any, of the holders of any series of preferred stock, special meetings of the stockholders of the Corporation may be called, at any time for any purpose or purposes as is proper for stockholder action under the DGCL by (1) the board of directors acting pursuant to a resolution duly adopted by a majority of the board of directors then in office, (2) the Chairperson of the board of directors, (3) the Chief Executive Officer, or (4) the Chief Executive Officer or secretary of the Corporation upon the written request of stockholder(s) owning (as defined below) at least 25% (in the aggregate) of the then voting power of all shares of the Corporation entitled to vote on the matters to be brought before the proposed special meeting, in each case subject to any procedures, terms and conditions as may be further set forth in the bylaws of the Corporation from time to time. Only those matters set forth in the notice of the special meeting or brought by or at the direction of the board of directors may be considered or acted upon at a special meeting of stockholders. In the case of a special meeting of stockholders called pursuant to the foregoing clause (4), the requesting holder(s) must (i) continue to own (for the holding period set forth in the bylaws of the Corporation as in effect from time to time) shares representing at least 25% (in the aggregate) of the then voting power of all shares of the Corporation entitled to vote on the matters to be brought before the proposed special meeting, (ii) provide information in writing regarding such stockholder(s), their stock ownership and the matters that they request to bring before the proposed special meeting and (iii) comply with procedures and other terms and conditions relating to special meetings as set forth in the bylaws of the Corporation from time to time. For purposes of this Article VII, a holder shall be deemed to "own" only those shares for which it possesses both (x) full voting and investment rights pertaining to such shares, and (y) a full economic interest in (including the opportunity for profit from and the risk of loss on) such shares, which term may be further defined in the bylaws of the Corporation from time to time.

ARTICLE VIII

8.1.General. The business and affairs of the Corporation shall be managed by or under the direction of the board of directors except as otherwise provided herein or required by law.

8.2.Election of directors. Unless and except that the bylaws of the Corporation shall so require, the election of directors need not be by written ballot.

8.3.Vacancies. Any director may resign at any time upon notice given in writing or electronic transmission to the Corporation. When one or more directors so resigns and the resignation is effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in this paragraph in the filling of other vacancies.

Vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director.

Whenever the holders of any class or classes of stock or series thereof are entitled to elect one or more directors by the provisions of this Certificate of Incorporation, vacancies and newly created directorships of such class or classes or series may be filled by a majority of the directors elected by such class or classes or series thereof then in office, or by a sole remaining director so elected.

Any director appointed in accordance with this Section 8.3 shall hold office for the remainder of the full term of the director in which the new directorship was created or the vacancy occurred and until such director's successor shall have been duly elected and qualified or until his or her earlier resignation, death or removal.

ARTICLE IX

To the fullest extent permitted by the DGCL as the same exists or as may hereafter be amended, no present or former director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director except for liability (a) for any breach of the director's duty of loyalty to the Corporation or its stockholders, (b) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (c) unlawful payments of dividends or unlawful stock repurchases or redemptions under Section 174 of the DGCL or (d) for any transaction from which the director derived an improper personal benefit. If the DGCL is amended after the effective date of this Certificate of Incorporation to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended. Neither any amendment nor repeal of this Article, nor the adoption of any provision of this Certificate of Incorporation inconsistent with this Article, shall eliminate or reduce the effect of this Article in respect of any matter occurring, or any cause of action, suit or claim that, but for this Article, would accrue or arise, prior to such amendment, repeal or adoption of an inconsistent provision.

ARTICLE X

The Corporation shall have the power to indemnify any person who was or is a party or is threatened to be made a party to, or testifies in, any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative in nature, by reason of the fact such person is or was a director, officer or employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, employee benefit plan, trust or other enterprise against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding to the full extent permitted by law, and the Corporation may adopt bylaws or enter into agreements with any such person for the purpose of providing for such indemnification.

ARTICLE XI

The Corporation reserves the right at any time, and from time to time, to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereafter prescribed by law; and all rights, preferences, powers and privileges of whatsoever nature conferred upon stockholders, directors or any other persons whomsoever by and pursuant to this Certificate of Incorporation in its present form or as hereafter amended are granted subject to the rights reserved in this article.

ARTICLE XII

In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, the board of directors of the Corporation is expressly authorized to make, alter and repeal the bylaws of the Corporation.

IN WITNESS WHEREOF, the undersigned has signed this Sixth Amended and Restated Certificate of Incorporation this 25th day of May 2022.

By: /s/ John G. McHutchison, A.O., M.D.
John G. McHutchison, A.O., M.D.
Chief Executive Officer and President

Exhibit 4.2

DESCRIPTION OF THE COMPANY'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

Assembly Biosciences, Inc. (Assembly, the Company, we, us and our) had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock does not purport to be complete and is subject to, and qualified in its entirety by, our Sixth Amended and Restated Certificate of Incorporation, as amended (our Certificate of Incorporation), and our amended and restated bylaws (our Bylaws), each of which is filed or incorporated by reference as an exhibit to the Annual Report on Form 10-K with which this Exhibit 4.2 is filed or incorporated by reference.

Authorized Capital Stock

Our authorized capital stock consists of 150,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of preferred stock, par value $0.001 per share.

Common Stock

The holders of our common stock are entitled to one vote per share on all matters to be voted on by the stockholders, and there are no cumulative voting rights.

The holders of common stock are entitled to receive ratable dividends, if any, payable when and as declared by our board of directors or any authorized committee thereof out of assets or funds legally available therefor, subject to any preferential rights that may be applicable to any outstanding preferred stock. In the event of a liquidation, dissolution or winding up of our company, after payment in full of all outstanding debts and other liabilities, the holders of common stock are entitled to share ratably in all remaining assets, subject to prior distribution rights of preferred stock, if any, then outstanding. No shares of common stock have preemptive rights or other subscription rights to purchase additional shares of common stock. There are no redemption or sinking fund provisions applicable to the common stock.

Listing

Our common stock is listed on The Nasdaq Global Select Market under the symbol "ASMB."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC. The transfer agent and registrar's address is 48 Wall Street, Floor 23, New York, NY 10005.

Preferred Stock

Our board of directors is authorized to issue up to 5,000,000 shares of preferred stock in one or more series without stockholder approval. Our board of directors may determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. The purpose of authorizing our board of directors to issue preferred stock in one or more series and determine the number of shares in the series and its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The existence of authorized but unissued shares of preferred stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. The rights of holders of our common stock described above will be subject to, and may be adversely affected by, the rights of any preferred stock that we may designate and issue in the future. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Provisions of our Certificate of Incorporation and Bylaws and Delaware Anti-Takeover Law

Certain provisions of the Delaware General Corporation Law (the DGCL), our Certificate of Incorporation and our Bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of us or considering unsolicited tender offers or other unilateral takeover proposals to first negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we believe that the advantages gained by protecting our ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our common stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Delaware Anti-Takeover Law

We are subject to the provisions of Section 203 of the DGCL (Section 203). In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with such person's affiliates and associates, owns, or did own within three years prior to such determination, 15% or more of the corporation's

voting stock. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding, for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or

- at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Charter Documents

Our Certificate of Incorporation and our Bylaws include a number of provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control or management of our company. First, our Certificate of Incorporation and our Bylaws provide that all stockholder action must be effected at a duly called meeting of stockholders and not by a consent in writing. Further, our Bylaws limit who may call special meetings of the stockholders. Our Certificate of Incorporation does not include a provision for cumulative voting for directors. Under cumulative voting, a minority stockholder holding a sufficient percentage of a class of shares may be able to ensure the election of one or more directors. Our Bylaws provide that the number of directors on our board, which may range from three to ten directors, shall be exclusively fixed by our board, which has set the number of directors at seven. Newly created directorships resulting from any increase in our authorized number of directors and any vacancies in our board resulting from death, resignation, retirement, disqualification or other cause (including removal from office by a vote of the stockholders) will be filled by a majority of our board then in office. Finally, our Bylaws establish procedures and other terms and conditions, including advance notice procedures, regarding special meeting requests by stockholders holding in the aggregate at least 25% of our outstanding common stock, nomination of candidates for election as directors and stockholder proposals. These and other provisions of our Certificate of Incorporation, our Bylaws and Delaware law could discourage potential acquisition proposals and could delay or prevent a change in control or management of our company.

Our Bylaws also provide that the Court of Chancery of the State of Delaware (or if such court does not have jurisdiction, the Superior Court of Delaware, or if such other court does not have jurisdiction, the United States District Court for the District of Delaware) will be 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 Certificate of Incorporation or our Bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This provision will not apply to litigation brought to enforce any liability or duty created by: the Securities Act of 1933, as amended; the Securities Exchange Act of 1934, as amended; or the rules and regulations thereunder. The enforceability of similar choice of forum provisions in other companies' organizational documents has been challenged in legal proceedings and, while the Delaware Supreme Court has upheld the validity of certain choice of forum provisions, it is possible that, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our Bylaws to be inapplicable or unenforceable.

Exhibit 10.11

EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (the "**Agreement**"), is entered into as of November 8, 2023 (the "**Execution Date**") with an effective date as of the first date of employment which is anticipated to be November 8, 2023 (the "**Effective Date**"), by and between Assembly Biosciences, Inc., a Delaware corporation with principal executive offices at 331 Oyster Point Blvd., South San Francisco, CA 94080 (the "**Company**"), and Anuj Gaggar, M.D., Ph.D. (the "**Executive**").

W I T N E S S E T H:

WHEREAS, the Company desires to employ the Executive as the Chief Medical Officer as of the Effective Date, and the Executive desires to accept employment by the Company as of the Effective Date; and

WHEREAS, the parties desire to enter into this Agreement, setting forth the terms and conditions of the Executive's employment with the Company.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the parties hereto hereby agree as follows:

1. Employment.

(a) Services. The Executive will be employed by the Company initially as its Chief Medical Officer, reporting to the Company's Chief Executive Officer, and shall perform such duties as are consistent with a position as Chief Medical Officer (the "**Services**"). The Executive agrees to perform such Services faithfully, to devote Executive's full working time, attention and energies to the business of the Company and, while Executive remains employed and subject to the terms of this Agreement, not to engage in any other business activity that is in conflict with Executive's duties and obligations to the Company.

(b) Acceptance. The Executive hereby accepts such employment and agrees to render the Services.

2. Term. The Executive's employment under this Agreement shall commence as of the Effective Date and shall continue on an "at-will" basis until terminated pursuant to Section 7 of this Agreement (the "**Term**").

3. Best Efforts. The Executive shall devote Executive's full business time, attention and energies to the business and affairs of the Company and shall use Executive's reasonable best efforts to advance the best interests of the Company and during the Term shall not be actively engaged in any other business activity, whether or not such business activity is pursued for gain, profit or other pecuniary advantage, that will interfere with the performance by the Executive of Executive's duties hereunder or the Executive's availability to perform such duties or that will adversely affect, or negatively reflect upon, the Company.

4. Compensation. During the Term, as full compensation for the performance by the Executive of his duties under this Agreement, the Company shall pay the Executive as follows:

(a) Base Salary. The Company shall pay the Executive an initial base salary at the annualized rate of four hundred ninety thousand dollars ($490,000). The base salary in effect at any given time is referred to herein as the "**Base Salary**." Payment shall be made in accordance with the Company's normal payroll practices, as they may be changed from time to time. The Base Salary will be reviewed by the Chief Executive Officer and the Board of Directors (the "**Board**"), or a committee thereof, no less frequently than annually.

(b) Annual Performance Bonus. Beginning in fiscal 2024, at the sole discretion of the Board (or a committee thereof), the Executive shall be eligible to receive an annual performance-based bonus during the Term (the "**Annual Performance Bonus**") targeted at forty percent (40%) of Executive's then current Base Salary based on the attainment by the Company and the Executive of performance objectives as established annually by the Chief Executive Officer with approval by the Board (or committee thereof). Any Annual Performance Bonus earned with respect to any fiscal year shall be based on the attainment by the Company of the performance objectives established by the Board (or a committee thereof) for the other named executive officers of the Company for such fiscal year and the Executive's individual performance objectives established by the Board (or a committee thereof) upon recommendation of the Chief Executive Officer, or as otherwise provided under any applicable bonus plan. The Annual Performance Bonus shall be payable in a single lump-sum as determined by the Board (or a committee thereof) in its sole discretion. Except as otherwise provided in this Agreement, to earn any particular Annual Performance Bonus, the Executive must, in addition to satisfying the performance objectives, remain employed on the date the Annual Performance Bonus is paid; *provided, further*, that the Annual Performance Bonus will be paid no later than seventy-five (75) days after the end of the period to which the Annual Performance Bonus pertains.

(c) Sign-on Bonus. The Company will pay the Executive a sign-on bonus in the gross amount of $100,000 (the "**Sign-on Bonus**"), less such taxes and applicable withholdings as required by law. The Sign-on Bonus will be payable to the Executive in a cash lump sum within 30 days following the Effective Date. If, prior to the six (6) month anniversary of the Effective Date, (i) the Executive terminates employment with the Company other than for Good Reason (as defined in Section 7(d)) or death or Disability (as defined in Section 7(b)) or (ii) the Company terminates the Executive for Cause (as defined in Section 7(a)), then the Executive will promptly repay to the Company 100% of the net amount of the Sign-On Bonus. If, on or after the six-month anniversary of the Effective Date and prior to the one-year anniversary of the Effective Date, the Executive terminates employment with the Company other than for Good Reason or death or Disability or the Company terminates Executive for Cause, then the Executive will promptly repay to the Company 66-2/3% of the net amount of the Sign-On Bonus. If, on or after the one-year anniversary of the Effective Date and prior to the eighteen (18) month anniversary of the Effective Date, the Executive terminates employment with the Company other than for Good Reason or death or Disability or the Company terminates Executive for Cause, then the Executive will promptly repay to the Company 33-1/3% of the net amount of the Sign-On Bonus. If the Executive is obligated under this Section 4(c) to repay to the Company the Sign-on Bonus, then the Company may, in its discretion and as permitted under applicable law, off-set all or part of the Executive's obligation under this Section 4(c) against amounts otherwise due to the Executive from the Company.

(d) Withholding. Amounts payable to the Executive under this Agreement, including Section 4 and Section 8, shall be net of all applicable federal, state and local taxes, social security and such other amounts as the Company may be required by law to withhold from such amounts.

(e) Equity. As a material inducement to accept the Company's offer of employment, the Company will recommend to the Board (or a committee thereof) that the Executive be granted, subject to the Executive's acceptance of this Agreement and commencement of employment, an option to purchase 500,000 shares of common stock of the Company (the "**New Hire Stock Option**"). As an inducement that is material to the Executive's employment with the Company, a portion of the New Hire Equity Awards will be granted to the Executive under each of (i) the Company's 2017 Inducement Award Plan (the "**2017 Inducement Plan**"), (ii) the Company's 2020 Inducement Award Plan (the "**2020 Inducement Plan**") and (iii) the Company's Amended and Restated 2014 Stock Incentive Plan (the "**2014 Plan**" and, together with the 2017 Inducement Plan and the 2020 Inducement Plan, the "**Plans**"). The grants to be made under the 2017 Inducement Plan and the 2020 Inducement Plan will be made pursuant to the inducement grant exception under Nasdaq Rule 5635(c)(4). The New Hire Stock Option will have the following terms:

(i) Subject to the Executive's continued employment and the terms of the Company's Plans and the applicable non-qualified stock option agreement entered into by the Executive and the Company pursuant to the Plans, the New Hire Stock Option will be granted as of the grant date, will have a term of ten years and the shares underlying the New Hire Stock Option shall vest in installments over four years with the first installment (representing approximately 25% of the shares) vesting on the first anniversary of the grant date and the balance vesting over the next three years thereafter in approximately equal monthly installments. The New Hire Stock Option will have an exercise price equal to the closing price of a common share of the Company on the Nasdaq Global Select Market on the grant date. The New Hire Stock Option shall be subject to accelerated vesting of time-based vesting awards in connection with a termination of employment to the extent and as provided in Section 8(b) of this Agreement. The New Hire Stock Option and any subsequently granted equity or stock-based awards under the Company's equity incentive plans, including stock options and restricted stock unit awards, will be collectively referred to in this Agreement as the "**Equity Awards**."

(f) Expenses. The Company shall provide the Executive with a corporate credit card for business use, and shall reimburse the Executive for all normal, usual and necessary expenses incurred by the Executive in furtherance of the business and affairs of the Company, including reasonable travel and entertainment, upon timely receipt by the Company of appropriate vouchers or other proof of the Executive's expenditures and otherwise in accordance with any expense reimbursement policy as may from time to time be adopted by the Company.

(g) Other Benefits. The Executive shall be entitled to all rights and benefits for which Executive shall be eligible under any benefit or other plans (including, without limitation, dental, medical, medical reimbursement and hospital plans, pension plans, employee stock purchase plans, profit sharing plans, bonus plans and other so-called "**Fringe Benefits**") as the Company shall make available to its senior executives from time to time, subject to the terms of such plans. In addition, if applicable, the Company shall reimburse the Executive for Executive's

reasonable licensing fees, continuing professional education, and other professional dues upon timely receipt by the Company of appropriate vouchers or other proof of the Executive's expenditures and otherwise in accordance with any expense reimbursement policy as may from time to time be adopted by the Company. The Company shall also name the Executive as a covered person under its Directors & Officers insurance policies.

(h) Vacation. The Executive will be entitled to paid vacation in accordance with the Company's vacation policy, as in effect from time to time.

5. Confidential Information and Inventions. The Executive agrees to execute and comply with the Company's standard form of Proprietary Information and Inventions Agreement, as it may be amended from time to time (the "**PIIA**").

6. Representations and Warranties.

(a) The Executive hereby represents and warrants to the Company as follows:

(i) Neither the execution or delivery of this Agreement nor the performance by the Executive of Executive's duties and other obligations hereunder violate or will violate any statute, law, determination or award, or conflict with or constitute a default or breach of any covenant or obligation under (whether immediately, upon the giving of notice or lapse of time or both) any prior employment agreement, contract, or other instrument to which the Executive is a party or by which he is bound.

(ii) The Executive has the full right, power and legal capacity to enter and deliver this Agreement and to perform Executive's duties and other obligations hereunder. This Agreement constitutes the legal, valid and binding obligation of the Executive enforceable against him in accordance with its terms. No approvals or consents of any persons or entities are required for the Executive to execute and deliver this Agreement or perform Executive's duties and other obligations hereunder.

(b) The Company hereby represents and warrants to the Executive that this Agreement and the employment of the Executive hereunder have been duly authorized by and on behalf of the Company, including, without limitation, by all required action by the Board.

7. Termination. The Executive's employment hereunder shall be terminated immediately upon the Executive's death and may be otherwise terminated as follows:

(a) The Executive's employment hereunder may be terminated by the Company for Cause as determined by the Chief Executive Officer. Any of the following actions by the Executive shall constitute "**Cause**":

(i) The willful failure or disregard or continuing refusal by the Executive to perform his duties hereunder;

(ii) Any act of willful or intentional misconduct, or a grossly negligent act by the Executive having the effect of injuring, in a material way (as determined in good-faith by the Company), the business or reputation of the Company, including but not limited to, any officer, director, or executive of the Company;

(iii)Willful misconduct by the Executive in carrying out his duties or obligations under this Agreement, including, without limitation, insubordination with respect to lawful directions received by the Executive from the Chief Executive Officer or from the Board having the effect of injuring, in a material way (as determined in good-faith by the Chief Executive Officer), the business or reputation of the Company;

(iv)The Executive's indictment of any felony or a misdemeanor involving moral turpitude (including entry of a nolo contendere plea);

(v) The determination by the Company, based upon clear and convincing evidence, after a reasonable and good-faith investigation by the Company following a written allegation by another employee of the Company, that the Executive engaged in some form of harassment or discrimination prohibited by law (including, without limitation, age, sex or race discrimination);

(vi)Any intentional misappropriation of the property of the Company, or embezzlement of its funds or assets (whether or not a misdemeanor or felony);

(vii)Breach by the Executive of any of the provisions of the PIIA; and

(viii)Breach by the Executive of any provision of this Agreement other than those contained in the PIIA, which is not cured by the Executive within thirty (30) business days after notice thereof is given to the Executive by the Company.

Except for a failure, misconduct, breach, or refusal which, by its nature, cannot reasonably be expected to be cured, the Executive shall have ten (10) business days from the delivery of written notice by the Company within which to cure any acts constituting Cause, unless a longer cure period is provided in the act constituting Cause described above; provided however, that, if the Company reasonably expects irreparable injury from a delay of ten (10) business days, the Company may give the Executive notice of such shorter period within which to cure as is reasonable under the circumstances, which may include the termination of the Executive's employment for Cause without notice and with immediate effect.

(b) The Executive's employment hereunder may be terminated by the Chief Executive Officer due to the Executive's Disability. For purposes of this Agreement, a termination for "**Disability**" shall occur (i) when the Chief Executive Officer has provided a written termination notice to the Executive supported by a written statement from a reputable independent physician mutually selected by the Company and the Executive, or the Executive's legal representatives in the event the Executive is unable to make such selection due to mental incapacity ("**Independent Physician**"), to the effect that the Executive shall have become so physically or mentally incapacitated as to be unable to resume, even with reasonable accommodation as may be required under the Americans With Disabilities Act, within the ensuing twelve (12) months, the Executive's employment hereunder by reason of physical or mental illness or injury, or (ii) upon rendering of a written termination notice by the Company after the Executive has been unable to substantially perform his duties hereunder, even with reasonable accommodation as may be required under the Americans With Disabilities Act, for one hundred twenty (120) or more consecutive days, or more than one hundred eighty (180) days in any consecutive twelve (12)

month period, by reason of any physical or mental illness or injury. For purposes of this Section 7(b), the Executive agrees to make himself available and to cooperate in any reasonable examination by an Independent Physician paid for by the Company. Notwithstanding the foregoing, nothing herein shall give the Company the right to terminate the Executive prior to discharging its obligations to the Executive, if any, under the Family and Medical Leave Act, the Americans With Disabilities Act, or any other applicable law. The Company shall reimburse the Executive for the Executive's actual cost of maintaining a supplementary long-term disability insurance policy during the Term up to a maximum reimbursement of $10,000 per year.

(c) The Executive's employment hereunder may be terminated by the Company (or its successor) by written notice to the Executive upon the occurrence of a Change of Control. For purposes of this Agreement, "**Change of Control**" means (i) the acquisition, directly or indirectly, following the Effective Date by any person (as such term is defined in Section 13(d) and 14(d)(2) of the Securities Exchange Act of 1934, as amended), in one transaction or a series of related transactions, of securities of the Company representing in excess of fifty percent (50%) of the combined voting power of the Company's then outstanding securities if such person or his or its affiliate(s) do not own in excess of fifty percent (50%) of such voting power on the Effective Date of this Agreement, (ii) the future disposition by the Company (whether direct or indirect, by sale of assets or stock, merger, consolidation or otherwise) of all or substantially all of its business and/or assets in one transaction or series of related transactions other than a merger effected exclusively for the purpose of changing the domicile of the Company, or (iii) a "corporate transaction" as defined in the Company equity incentive plans under which the Executive has been granted Equity Awards. Notwithstanding the foregoing, if the Change of Control does not constitute a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the assets of the Company, within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "**Code**"), the amount of cash severance payable pursuant to Section 8(b), if any, shall be paid in equal installments in accordance with the Company's then payroll practice over a 12-month period. Solely for purposes of Section 409A of the Code, each installment payment under this Agreement is considered a separate payment.

(d) The Executive's employment hereunder may be voluntarily terminated by the Executive for Good Reason. For purposes of this Agreement, "Good Reason" shall mean any of the following: (i) any material reduction by the Company of the Executive's duties, or responsibilities or authority that, taken as a whole, results in a material diminution of position; provided, however, that a change in the Executive's title or reporting relationship shall not by itself constitute a termination by the Executive for Good Reason under this clause (i); (ii) any material (meaning 10% or more) reduction by the Company of the Executive's Base Salary and/or target Annual Performance Bonus payable hereunder (it being understood that an across-the-board reduction applicable to all similarly situated employees of the Company, including the Executive, shall not be deemed a reduction for purposes of this definition); (iii) in connection with a Change of Control or within the COC Period (as defined in Section 8(b) below), a material adverse change in the reporting structure or title applicable to the Executive, including an adverse change arising from a material diminution in the authority, duties or responsibilities of the supervisor to whom the Executive is required to report (e.g., the Executive no longer reports to the Chief Executive Officer of the Company or its successor); (iv) any requirement by the Company, without the Executive's prior written consent, that the Executive locate the Executive's residence or primary place of employment to a location outside a 50-mile radius of such location mutually agreed upon

between the Company and the Executive as of the Effective Date, or such other location that the Company and the Executive may mutually agree upon and designate from time to time during the Term; or (v) a material breach by the Company of Section 6(b) of this Agreement which is not cured by the Company within thirty (30) days after written notice thereof is given to the Company by the Executive. However, notwithstanding the above, Good Reason shall not exist unless: (x) the Executive notifies in writing the Chief Executive Officer within thirty (30) days of the initial existence of one of the adverse events described above, and (y) the Company fails to correct the adverse event within thirty (30) days of such written notice, and (z) the Executive's voluntary termination because of the existence of one or more of the adverse events described above occurs within ninety (90) days of the initial existence of the event.

(e) The Executive's employment may be terminated by the Company without Cause by delivery of written notice to the Executive effective the date of delivery of such notice. For the avoidance of doubt, termination of the Executive's employment due to his death or Disability does not constitute a termination for Cause.

(f) The Executive's employment may be terminated by the Executive in the absence of Good Reason by delivery of written notice to the Company effective fifteen (15) days after the date of delivery of such notice.

8. Compensation upon Termination.

(a) Accrued Benefits. Upon termination of the Executive's employment by either party regardless of the cause or reason, the Executive shall be entitled to the following, referred to herein as the "**Accrued Benefits**": (i) payment for any accrued, unpaid Base Salary through the termination date; (ii) if provided for under the Company's vacation plan or policy or required by applicable law, payment for any accrued, unused vacation days through the termination date; and (iii) reimbursement for any approved business expenses that the Executive has timely submitted for reimbursement in accordance with the Company's business expense reimbursement policy or practice. Except as otherwise expressly provided by this Agreement, the Company shall have no further payment obligations to the Executive and all Equity Awards that have not vested as of the termination date shall be forfeited to the Company as of such date. Subject to this Section 8, the vested portion of any stock options held by the Executive as of the Executive's termination date shall remain exercisable for ninety (90) days following such termination.

(b) Change of Control Separation Benefits. If the Executive's employment is terminated by the Company due to Disability pursuant to Section 7(b), by the Company without Cause pursuant to Section 7(e) or by the Executive for Good Reason pursuant to Section 7(d) and such termination occurs during the period beginning on the Change of Control and ending twelve (12) months immediately following such Change of Control (the "**COC Period**"), *provided* that the Executive signs and does not revoke a general release of claims against the Company within the time period specified therein (which time period shall not exceed sixty (60) days), in form and substance satisfactory to the Company (the "**Release**"), then the Company shall provide the following benefits to the Executive, referred to herein as the "**Change of Control Separation Benefits**": (i) a lump sum payment equal to twelve (12) months of the Executive's then-current Base Salary; (ii) the full target Annual Performance Bonus for the year in which such termination occurs, less any installments paid in advance (items (i) and (ii) being the "**Change of**

Control Separation Pay"); (iii) immediate vesting in full of all Equity Awards with time based vesting; and (iv) if the Executive properly and timely elects to continue his health insurance benefits under COBRA or applicable state continuation coverage after the termination date, reimbursement for the portion of Executive's health continuation coverage premiums that the Company would have paid had the Executive remained employed by the Company until the earlier of (A) the twelve (12) months following the month in which the Executive's termination date occurs, or (B) the maximum period permitted by applicable law, provided that the Company's obligation to pay a portion of the Executive's health continuation coverage premiums will terminate if Executive becomes eligible for health insurance benefits from another employer during the reimbursement period. Subject to the Release being effective, the Change of Control Separation Pay will be paid within sixty (60) days after the termination date; *provided, however*, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payments, to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall be paid no earlier than the first Company payroll date in the second calendar year and, in any case, by the last day of such 60-day period.

(c) Base Separation Benefits. If the Executive's employment is terminated during the Term and outside of the COC Period as a result of the Executive's Disability pursuant to Section 7(b), by the Company without Cause pursuant to Section 7(e), or by the Executive for Good Reason pursuant to Section 7(d), *provided* that the Executive signs and does not revoke the Release within the time period specified therein (which time period shall not exceed sixty (60) days), then the Company shall provide the following benefits to the Executive, referred to herein as the "**Base Separation Benefits**": (i) the continued payment in installments of the Executive's then-current Base Salary for a period of twelve (12) months following the termination date (the "**Base Separation Pay**"); and (ii) if the Executive properly and timely elects to continue Executive's health insurance benefits under COBRA or applicable state continuation coverage after the termination date, reimbursement for the portion of the Executive's health continuation coverage premiums that the Company would have paid had the Executive remained employed by the Company until the earlier of (A) the twelve (12) months following the month in which the Executive's termination date occurs, or (B) the maximum period permitted by applicable law, provided that the Company's obligation to pay a portion of the Executive's health continuation coverage premiums will terminate if he becomes eligible for health insurance benefits from another employer during the reimbursement period. The first installment of the Base Separation Pay will be paid on the Company's first regular payday occurring following the effectiveness of the Release in an amount equal to the sum of payments of Base Salary that would have been paid if Executive had remained in employment for the period from the termination date through the payment date. The remaining installments will be paid until the end of the 12-month period at the same rate as the Base Salary in accordance with the Company's normal payroll practices for its employees. Notwithstanding the foregoing, if the 60-day period for the execution and non-revocation of the Release begins in one calendar year and ends in a second calendar year, the Base Separation Pay, to the extent it qualifies as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall begin to be paid no earlier than the first Company payroll date in the second calendar year and, in any case, by the last day of such 60-day period; *provided, however*, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the termination date. The Executive understands that if the Executive is eligible to receive the Base Separation Benefits, such Base Separation Benefits shall be in lieu of and not in addition to the Change of Control Separation Benefits described in Section 8(b) of this

Agreement. Notwithstanding the foregoing, if the Executive is entitled to receive the Base Separation Benefits but violates any provisions of this Agreement, the PIIA or any other agreement entered into by the Executive and the Company after termination of employment, the Company will be entitled to immediately stop paying any further installments of the Base Separation Benefits.

(d) This Section 8 sets forth the only obligations of the Company with respect to the termination of the Executive's employment with the Company, except as otherwise required by law, and the Executive acknowledges that, upon the termination of the Executive's employment, the Executive shall not be entitled to any payments or benefits which are not explicitly provided in Section 8.

(e) Upon termination of the Executive's employment hereunder for any reason, the Executive shall be deemed to have resigned as director and/or officer of the Company and each subsidiary of the Company, to the extent applicable, effective as of the date of such termination, unless otherwise requested by the Board.

(f) The provisions of this Section 8 shall survive any termination of this Agreement.

9. Section 409A. The intent of the parties to this Agreement is that the payments, compensation and benefits under this Agreement be exempt from or comply with Section 409A of the Code and the regulations and guidance promulgated thereunder (collectively, "**Section 409A**") and, in this connection, the following shall be applicable:

(a) To the greatest extent possible, this Agreement shall be interpreted to be exempt from or in compliance with Section 409A.

(b) If any severance, compensation, or benefit required by this Agreement is to be paid in a series of installment payments, each individual payment in the series shall be considered a separate payment for purposes of Section 409A.

(c) If any severance, compensation, or benefit required by this Agreement that constitutes "nonqualified deferred compensation" within the meaning of Section 409A is considered to be paid on account of "separation from service" within the meaning of Section 409A, and the Executive is a "specified employee" within the meaning of Section 409A, no payments of any of such severance, compensation, or benefit shall be made until the earlier of six (6) months plus one (1) day after such separation from service or the Executive's death (the "**New Payment Date**"). The aggregate amount of any such payments that would have otherwise been paid during the period between the date of separation from service and the New Payment Date shall be paid to the Executive or his estate in a lump sum payment on the New Payment Date. Thereafter, any severance, compensation, or benefit required by this Agreement that remains outstanding as of the day immediately following the New Payment Date shall be paid without delay over the time period originally scheduled, in accordance with the terms of this Agreement.

(d) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Executive's termination of employment, then such payments or benefits shall be payable only upon the Executive's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A 1(h).

(e) The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

(f) The provisions of this Section 9 shall survive any termination of this Agreement.

10. Section 280G.

(a) Notwithstanding any other provision of this Agreement or any other plan, arrangement or agreement to the contrary, if any of the payments or benefits provided or to be provided by the Company or its affiliates to the Executive or for the Executive's benefit pursuant to the terms of this Agreement or otherwise ("**Covered Payments**") constitute parachute payments ("**Parachute Payments**") within the meaning of Section 280G of the Code and would, but for this Section 10 be subject to the excise tax imposed under Section 4999 of the Code (or any successor provision thereto) or any similar tax imposed by state or local law or any interest or penalties with respect to such taxes (collectively, the "**Excise Tax**"), then prior to making the Covered Payments, a calculation shall be made comparing (i) the Net Benefit (as defined below) to the Executive of the Covered Payments after payment of the Excise Tax to (ii) the Net Benefit to the Executive if the Covered Payments are limited to the extent necessary to avoid being subject to the Excise Tax. Only if the amount calculated under (i) above is less than the amount under (ii) above will the Covered Payments be reduced to the minimum extent necessary to ensure that no portion of the Covered Payments is subject to the Excise Tax (that amount, the "**Reduced Amount**"). "**Net Benefit**" shall mean the present value of the Covered Payments net of all federal, state, local, foreign income, employment and excise taxes.

(b) Any such reduction shall be made in accordance with Section 409A of the Code and the following: (i) the Covered Payments which do not constitute nonqualified deferred compensation subject to Section 409A of the Code shall be reduced first; and (ii) all other Covered Payments shall then be reduced as follows: (A) cash payments shall be reduced before non-cash payments; and (B) payments to be made on a later payment date shall be reduced before payments to be made on an earlier payment date.

(c) Any determination required under this Section 10 shall be made in writing in good faith by the accounting firm that was the Company's independent auditor immediately before the Change of Control (the "**Accounting Firm**"). The Accounting Firm shall provide detailed supporting calculations to the Company and the Executive as requested by the Company or the Executive. The Company and the Executive shall provide the Accounting Firm with such information and documents as the Accounting Firm may reasonably request in order to make a

determination under this Section 10. For purposes of making the calculations and determinations required by this Section 10, the Accounting Firm may rely on reasonable, good faith assumptions and approximations concerning the application of Section 280G and Section 4999 of the Code. The Accounting Firm's determinations shall be final and binding on the Company and the Executive. The Company shall be responsible for all fees and expenses incurred by the Accounting Firm in connection with the calculations required by this Section 10.

(d) It is possible that after the determinations and selections made pursuant to this Section 10 the Executive will receive Covered Payments that are in the aggregate more than the amount provided under this Section 10 ("**Overpayment**") or less than the amount provided under this Section 10 ("**Underpayment**").

(i) In the event that: (A) the Accounting Firm determines, based upon the assertion of a deficiency by the Internal Revenue Service against either the Company or the Executive which the Accounting Firm believes has a high probability of success, that an Overpayment has been made or (B) it is established pursuant to a final determination of a court or an Internal Revenue Service proceeding that has been finally and conclusively resolved that an Overpayment has been made, then the Executive shall pay any such Overpayment to the Company.

(ii) In the event that: (A) the Accounting Firm, based upon controlling precedent or substantial authority, determine that an Underpayment has occurred or (B) a court of competent jurisdiction determines that an Underpayment has occurred, any such Underpayment will be paid promptly by the Company to or for the benefit of the Executive.

11. Miscellaneous.

(a) This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the State of California, without giving effect to its principles of conflicts of laws.

(b) In the event of any dispute arising out of, or relating to, this Agreement or the breach thereof, or regarding the interpretation thereof, the parties agree to submit any differences to nonbinding mediation prior to pursuing resolution through the courts. The parties hereby submit to the exclusive jurisdiction of the state and federal courts situated in San Francisco County, California, and agree that service of process in such court proceedings shall be satisfactorily made upon each other if sent by registered mail addressed to the recipient at the address referred to in Section 11(g) below.

(c) This Agreement shall be binding upon and inure to the benefit of the parties hereto, and their respective heirs, legal representatives, successors and permitted assigns.

(d) This Agreement, and the Executive's rights and obligations hereunder, may not be assigned by the Executive. The rights and obligations of the Company under this Agreement shall inure to the benefit of and shall be binding upon the successors and assigns of the Company, including any successors or assigns in connection with any sale, transfer or other disposition of all or substantially all of its business or assets.

(e) This Agreement cannot be amended orally, or by any course of conduct or dealing, but only by a written agreement signed by the parties hereto.

(f) The failure of either party to insist upon the strict performance of any of the terms, conditions and provisions of this Agreement shall not be construed as a waiver or relinquishment of future compliance therewith, and such terms, conditions and provisions shall remain in full force and effect. No waiver of any term or condition of this Agreement on the part of either party shall be effective for any purpose whatsoever unless such waiver is in writing and signed by such party.

(g) All notices, requests, consents and other communications, required or permitted to be given hereunder, shall be in writing and shall be delivered personally or by an overnight courier service or sent by registered or certified mail, postage prepaid, return receipt requested, to the Executive at the last address of record in his personnel file and to the Company at the address for its corporate headquarters, and shall be deemed given when so delivered personally or by overnight courier, or, if mailed, five days after the date of deposit in the United States mail. Either party may designate another address, for receipt of notices hereunder by giving notice to the other party in accordance with this Section 11(g).

(h) This Agreement sets forth the entire agreement and understanding of the parties relating to the subject matter hereof, and supersedes all prior agreements, arrangements and understandings, written or oral, relating to the subject matter hereof. No representation, promise or inducement has been made by either party that is not embodied in this Agreement, and neither party shall be bound by or liable for any alleged representation, promise or inducement not so set forth.

(i) As used in this Agreement, "affiliate" of a specified person or entity shall mean and include any person or entity controlling, controlled by or under common control with the specified person or entity.

(j) The section headings contained herein are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

(k) This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same original, binding document. Any facsimile, PDF reproduction of original signatures or other electronic transmission of a signed counterpart shall be deemed to be an original counterpart and any signature appearing thereon shall be deemed to be an original signature. Each party agrees that the electronic signatures of the parties included in this Agreement, including via DocuSign®, are intended to authenticate this writing and to have the same force and effect as manual signatures.

[*Remainder of Page Intentionally Left Blank – Signature Page Follows*]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement and intend it to be effective as of the Effective Date by proper person thereunto duly authorized.

ASSEMBLY BIOSCIENCES, INC.

By: /s/ Jason A. Okazaki
Name: Jason A. Okazaki
Title: Chief Executive Officer and President

EXECUTIVE

/s/Anuj Gaggar, M.D., Ph.D.
Name: Anuj Gaggar, M.D., Ph.D.

Exhibit 10.12

EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (the "**Agreement**"), is entered into as of February 1, 2022 (the "**Execution Date**") with an effective date February 10, 2022 (the "**Effective Date**"), by and between Assembly Biosciences, Inc., a Delaware corporation with principal executive offices at 331 Oyster Point Blvd., Fourth Floor, South San Francisco, CA 94080 (the "**Company**"), and Nicole S. White, Ph.D. (the "**Employee**").

W I T N E S S E T H:

WHEREAS, the Company desires to promote the Employee to Chief Manufacturing Officer as of the Effective Date, and the Employee desires to accept this promotion as of the Effective Date; and

WHEREAS, the parties desire to enter into this Agreement, setting forth the terms and conditions of the Employee's employment with the Company;

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the parties hereto hereby agree as follows:

1. Employment.

(a) Services. The Employee will be employed by the Company as its Chief Manufacturing Officer, reporting to the Company's Chief Executive Officer, and shall perform such duties as are consistent with a position as Chief Manufacturing Officer (the "**Services**"). The Employee agrees to perform such Services faithfully, to devote Employee's full working time, attention and energies to the business of the Company and, while Employee remains employed and subject to the terms of this Agreement, not to engage in any other business activity that is in conflict with Employee's duties and obligations to the Company.

(b) Acceptance. The Employee hereby accepts such employment and agrees to render the Services.

2. Term. The Employee's employment under this Agreement shall commence as of the Effective Date and shall continue on an "at-will" basis until terminated pursuant to Section 7 of this Agreement (the "**Term**").

3. Best Efforts. The Employee shall devote Employee's full business time, attention and energies to the business and affairs of the Company and shall use Employee's reasonable best efforts to advance the best interests of the Company and during the Term shall not be actively engaged in any other business activity, whether or not such business activity is pursued for gain, profit or other pecuniary advantage, that will interfere with the performance by the Employee of Employee's duties hereunder or the Employee's availability to perform such duties or that will adversely affect, or negatively reflect upon, the Company.

4. Compensation. During the Term, as full compensation for the performance by the Employee of his duties under this Agreement, the Company shall pay the Employee as follows:

(a) Base Salary. The Company shall pay the Employee a base salary at the annualized rate of four hundred thousand dollars ($400,000). The base salary in effect at any given time is referred to herein as the "**Base Salary**." Payment shall be made in accordance with the Company's normal payroll practices, as they may be changed from time to time. The Base Salary will be reviewed by the Chief Executive Officer and the Board of Directors (the "**Board**"), or a committee thereof, no less frequently than annually.

(b) Annual Performance Bonus. At the sole discretion of the Board (or a committee thereof), the Employee shall be eligible to receive an annual performance-based bonus during the Term (the "**Annual Performance Bonus**") targeted at forty percent (40%) of Employee's then current Base Salary based on the attainment by the Employee of performance objectives as established annually by the Chief Executive Officer. The Annual Performance Bonus shall be payable in a single lump-sum as determined by the Board (or a committee thereof) in its sole discretion. Except as otherwise provided in this Agreement, to earn any particular Annual Performance Bonus, the Employee must, in addition to satisfying the performance objectives, remain employed on the date the Annual Performance Bonus is paid; *provided, further*, that the Annual Performance Bonus will be paid no later than seventy-five (75) days after the end of the period to which the Annual Performance Bonus pertains.

(c) Withholding. Amounts payable to the Employee under this Agreement, including Section4 and Section 8, shall be net of all applicable federal, state and local taxes, social security and such other amounts as the Company may be required by law to withhold from such amounts.

(d) Equity. From time to time, subject to and upon the approval by the Board (or a committee thereof), the Company may grant to the Employee equity awards to purchase or receive shares of common stock of the Company (the "**Equity Awards**"). The Equity Awards will contain such terms and conditions as may be approved by the Board (or a committee thereof).

(e) Expenses. The Company shall provide the Employee with a corporate credit card for business use, and shall reimburse the Employee for all normal, usual and necessary expenses incurred by the Employee in furtherance of the business and affairs of the Company, including reasonable travel and entertainment, upon timely receipt by the Company of appropriate vouchers or other proof of the Employee's expenditures and otherwise in accordance with any expense reimbursement policy as may from time to time be adopted by the Company.

(f) Other Benefits. The Employee shall be entitled to all rights and benefits for which Employee shall be eligible under any benefit or other plans (including, without limitation, dental, medical, medical reimbursement and hospital plans, pension plans, employee stock purchase plans, profit sharing plans, bonus plans and other so-called "**Fringe Benefits**") as the Company shall make available to its senior executives from time to time, subject to the terms of such plans. In addition, if applicable, the Company shall reimburse the Employee for Employee's reasonable licensing fees, continuing professional education, and other professional dues upon timely receipt by the Company of appropriate vouchers or other proof of the Employee's

expenditures and otherwise in accordance with any expense reimbursement policy as may from time to time be adopted by the Company. The Company shall also name the Employee as a covered person under its Directors & Officers insurance policies.

(g) Vacation. The Employee will be entitled to paid vacation in accordance with the Company's vacation policy, as in effect from time to time.

5. Confidential Information and Inventions. The Employee agrees to continue to comply with the Company's standard form of Proprietary Information and Inventions Agreement, as it may be amended from time to time (the "**PIIA**").

6. Representations and Warranties.

(a) The Employee hereby represents and warrants to the Company as follows:

(i) Neither the execution or delivery of this Agreement nor the performance by the Employee of Employee's duties and other obligations hereunder violate or will violate any statute, law, determination or award, or conflict with or constitute a default or breach of any covenant or obligation under (whether immediately, upon the giving of notice or lapse of time or both) any prior employment agreement, contract, or other instrument to which the Employee is a party or by which he is bound.

(ii) The Employee has the full right, power and legal capacity to enter and deliver this Agreement and to perform Employee's duties and other obligations hereunder. This Agreement constitutes the legal, valid and binding obligation of the Employee enforceable against him in accordance with its terms. No approvals or consents of any persons or entities are required for the Employee to execute and deliver this Agreement or perform Employee's duties and other obligations hereunder.

(b) The Company hereby represents and warrants to the Employee that this Agreement and the employment of the Employee hereunder have been duly authorized by and on behalf of the Company, including, without limitation, by all required action by the Board.

7. Termination. The Employee's employment hereunder shall be terminated immediately upon the Employee's death and may be otherwise terminated as follows:

(a) The Employee's employment hereunder may be terminated by the Company for Cause as determined by the Chief Executive Officer. Any of the following actions by the Employee shall constitute "**Cause**":

(i) The willful failure or disregard or continuing refusal by the Employee to perform his duties hereunder;

(ii) Any act of willful or intentional misconduct, or a grossly negligent act by the Employee having the effect of injuring, in a material way (as determined in good-faith by the Company), the business or reputation of the Company, including but not limited to, any officer, director, or executive of the Company;

(iii)Willful misconduct by the Employee in carrying out his duties or obligations under this Agreement, including, without limitation, insubordination with respect to lawful directions received by the Employee from the Chief Executive Officer or from the Board having the effect of injuring, in a material way (as determined in good-faith by the Chief Executive Officer), the business or reputation of the Company;

(iv)The Employee's indictment of any felony or a misdemeanor involving moral turpitude (including entry of a nolo contendere plea);

(v) The determination by the Company, based upon clear and convincing evidence, after a reasonable and good-faith investigation by the Company following a written allegation by another employee of the Company, that the Employee engaged in some form of harassment or discrimination prohibited by law (including, without limitation, age, sex or race discrimination);

(vi)Any intentional misappropriation of the property of the Company, or embezzlement of its funds or assets (whether or not a misdemeanor or felony);

(vii)Breach by the Employee of any of the provisions of the PIIA; and

(viii)Breach by the Employee of any provision of this Agreement other than those contained in the PIIA, which is not cured by the Employee within thirty (30) business days after notice thereof is given to the Employee by the Company.

Except for a failure, misconduct, breach, or refusal which, by its nature, cannot reasonably be expected to be cured, the Employee shall have ten (10) business days from the delivery of written notice by the Company within which to cure any acts constituting Cause, unless a longer cure period is provided in the act constituting Cause described above; provided however, that, if the Company reasonably expects irreparable injury from a delay of ten (10) business days, the Company may give the Employee notice of such shorter period within which to cure as is reasonable under the circumstances, which may include the termination of the Employee's employment for Cause without notice and with immediate effect.

(b) The Employee's employment hereunder may be terminated by the Chief Executive Officer due to the Employee's Disability. For purposes of this Agreement, a termination for "**Disability**" shall occur (i) when the Chief Executive Officer has provided a written termination notice to the Employee supported by a written statement from a reputable independent physician mutually selected by the Company and the Employee, or the Employee's legal representatives in the event the Employee is unable to make such selection due to mental incapacity, to the effect that the Employee shall have become so physically or mentally incapacitated as to be unable to resume, even with reasonable accommodation as may be required under the Americans With Disabilities Act, within the ensuing twelve (12) months, the Employee's employment hereunder by reason of physical or mental illness or injury, or (ii) upon rendering of a written termination notice by the Company after the Employee has been unable to substantially perform his duties hereunder, even with reasonable accommodation as may be required under the Americans With Disabilities Act, for one hundred twenty (120) or more consecutive days, or more than one hundred eighty (180) days in any consecutive twelve (12) month period, by reason of any

physical or mental illness or injury. For purposes of this Section 7(b), the Employee agrees to make himself available and to cooperate in any reasonable examination by a reputable independent physician mutually selected by the Company and the Employee and paid for by the Company. Notwithstanding the foregoing, nothing herein shall give the Company the right to terminate the Employee prior to discharging its obligations to the Employee, if any, under the Family and Medical Leave Act, the Americans With Disabilities Act, or any other applicable law. The Company shall reimburse the Employee for the Employee's actual cost of maintaining a supplementary long-term disability insurance policy during the Term up to a maximum reimbursement of $10,000 per year.

(c) The Employee's employment hereunder may be terminated by the Company (or its successor) by written notice to the Employee upon the occurrence of a Change of Control. For purposes of this Agreement, "**Change of Control**" means (i) the acquisition, directly or indirectly, following the Effective Date by any person (as such term is defined in Section 13(d) and 14(d)(2) of the Securities Exchange Act of 1934, as amended), in one transaction or a series of related transactions, of securities of the Company representing in excess of fifty percent (50%) of the combined voting power of the Company's then outstanding securities if such person or his or its affiliate(s) do not own in excess of fifty percent (50%) of such voting power on the Effective Date of this Agreement, (ii) the future disposition by the Company (whether direct or indirect, by sale of assets or stock, merger, consolidation or otherwise) of all or substantially all of its business and/or assets in one transaction or series of related transactions other than a merger effected exclusively for the purpose of changing the domicile of the Company, or (iii) a "corporate transaction" as defined in the Company equity incentive plans under which the Employee has been granted Equity Awards. Notwithstanding the foregoing, if the Change of Control does not constitute a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the assets of the Company, within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "**Cod**e"), the amount of cash severance payable pursuant to Section 8(b), if any, shall be paid in equal installments in accordance with the Company's then payroll practice over a 12-month period. Solely for purposes of Section 409A of the Code, each installment payment under this Agreement is considered a separate payment.

(d) The Employee's employment hereunder may be voluntarily terminated by the Employee for Good Reason. For purposes of this Agreement, "**Good Reason**" shall mean any of the following: (i) any material reduction by the Company of the Employee's duties, or responsibilities or authority that, taken as a whole, results in a material diminution of position; provided, however, that a change in the Employee's title or reporting relationship shall not by itself constitute a termination by the Employee for Good Reason under this clause (i); (ii) any material (meaning 10% or more) reduction by the Company of the Employee's Base Salary and/or target Annual Performance Bonus payable hereunder (it being understood that an across-the-board reduction applicable to all similarly situated employees of the Company, including the Employee, shall not be deemed a reduction for purposes of this definition); (iii) in connection with a Change of Control or within the COC Period (as defined in Section 8(b) below) following a Change of Control, a material adverse change in the reporting structure or title applicable to the Employee, including an adverse change arising from a material diminution in the authority, duties or responsibilities of the supervisor to whom the Employee is required to report (e.g., the Employee no longer reports to the Chief Executive Officer of the Company or its successor); (iv) any requirement by the Company, without the Employee's prior written consent, that the Employee

locate the Employee's residence or primary place of employment to a location outside a 50-mile radius of such location mutually agreed upon between the Company and the Employee as of the Effective Date, or such other location that the Company and the Employee may mutually agree upon and designate from time to time during the Term; or (v) a material breach by the Company of Section 6(b) of this Agreement which is not cured by the Company within thirty (30) days after written notice thereof is given to the Company by the Employee. However, notwithstanding the above, Good Reason shall not exist unless: (x) the Employee notifies in writing the Chief Executive Officer within thirty (30) days of the initial existence of one of the adverse events described above, and (y) the Company fails to correct the adverse event within thirty (30) days of such written notice, and (z) the Employee's voluntary termination because of the existence of one or more of the adverse events described above occurs within ninety (90) days of the initial existence of the event.

(e) The Employee's employment may be terminated by the Company without Cause by delivery of written notice to the Employee effective the date of delivery of such notice. For the avoidance of doubt, termination of the Employee's employment due to his death or Disability does not constitute a termination for Cause.

(f) The Employee's employment may be terminated by the Employee in the absence of Good Reason by delivery of written notice to the Company effective fifteen (15) days after the date of delivery of such notice.

8. Compensation upon Termination.

(a) Accrued Benefits. Upon termination of the Employee's employment by either party regardless of the cause or reason, the Employee shall be entitled to the following, referred to herein as the "**Accrued Benefits**": (i) payment for any accrued, unpaid Base Salary through the termination date; (ii) if provided for under the Company's vacation plan or policy or required by applicable law, payment for any accrued, unused vacation days through the termination date; and (iii) reimbursement for any approved business expenses that the Employee has timely submitted for reimbursement in accordance with the Company's business expense reimbursement policy or practice. Except as otherwise expressly provided by this Agreement, the Company shall have no further payment obligations to the Employee and all Equity Awards that have not vested as of the termination date shall be forfeited to the Company as of such date. Subject to this Section 8, the vested portion of any stock options held by the Employee as of the Employee's termination date shall remain exercisable for ninety (90) days following such termination.

(b) Change of Control Separation Benefits. If the Employee's employment is terminated by the Company due to Disability pursuant to Section 7(b), by the Company without Cause pursuant to Section 7(e) or by the Employee for Good Reason pursuant to Section 7(d) and such termination occurs during the period beginning on the Change of Control and ending twelve (12) months immediately following such Change of Control (the "**COC Period**"), *provided* that the Employee signs and does not revoke a general release of claims against the Company within the time period specified therein (which time period shall not exceed sixty (60) days), in form and substance satisfactory to the Company (the "**Release**"), then the Company shall provide the following benefits to the Employee, referred to herein as the "**Change of Control Separation Benefits**": (i) a lump sum payment equal to twelve (12) months of the Employee's then-current

Base Salary; (ii) the full target Annual Performance Bonus for the year in which such termination occurs, less any installments paid in advance (items (i) and (ii) being the "**Change of Control Separation Pay**"); (iii) immediate vesting in full of all Equity Awards with time based vesting; and (iv) if the Employee properly and timely elects to continue his health insurance benefits under COBRA or applicable state continuation coverage after the termination date, reimbursement for the portion of Employee's health continuation coverage premiums that the Company would have paid had the Employee remained employed by the Company until the earlier of (A) the twelve (12) months following the month in which the Employee's termination date occurs, or (B) the maximum period permitted by applicable law, provided that the Company's obligation to pay a portion of the Employee's health continuation coverage premiums will terminate if Employee becomes eligible for health insurance benefits from another employer during the reimbursement period. Subject to the Release being effective, the Change of Control Separation Pay will be paid within sixty (60) days after the termination date; *provided, however*, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payments, to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall be paid no earlier than the first Company payroll date in the second calendar year and, in any case, by the last day of such 60-day period.

(c) Base Separation Benefits. If the Employee's employment is terminated during the Term and outside of the COC Period as a result of the Employee's Disability pursuant to Section 7(b), by the Company without Cause pursuant to Section 7(e), or by the Employee for Good Reason pursuant to Section 7(d), *provided* that the Employee signs and does not revoke the Release within the time period specified therein (which time period shall not exceed sixty (60) days), then the Company shall provide the following benefits to the Employee, referred to herein as the "**Base Separation Benefits**": (i) the continued payment in installments of the Employee's then-current Base Salary for a period of twelve (12) months following the termination date (the "**Base Separation Pay**"); and (ii) if the Employee properly and timely elects to continue Employee's health insurance benefits under COBRA or applicable state continuation coverage after the termination date, reimbursement for the portion of the Employee's health continuation coverage premiums that the Company would have paid had the Employee remained employed by the Company until the earlier of (A) the twelve (12) months following the month in which the Employee's termination date occurs, or (B) the maximum period permitted by applicable law, provided that the Company's obligation to pay a portion of the Employee's health continuation coverage premiums will terminate if he becomes eligible for health insurance benefits from another employer during the reimbursement period. The first installment of the Base Separation Pay will be paid on the Company's first regular payday occurring following the effectiveness of the Release in an amount equal to the sum of payments of Base Salary that would have been paid if Employee had remained in employment for the period from the termination date through the payment date. The remaining installments will be paid until the end of the 12-month period at the same rate as the Base Salary in accordance with the Company's normal payroll practices for its employees. Notwithstanding the foregoing, if the 60-day period for the execution and non-revocation of the Release begins in one calendar year and ends in a second calendar year, the Base Separation Pay, to the extent it qualifies as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall begin to be paid no earlier than the first Company payroll date in the second calendar year and, in any case, by the last day of such 60-day period; *provided, however*, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the termination date. The Employee understands that if the Employee is eligible to receive the Base Separation Benefits, such Base Separation Benefits shall be in lieu of

and not in addition to the Change of Control Separation Benefits described in Section 8(b) of this Agreement. Notwithstanding the foregoing, if the Employee is entitled to receive the Base Separation Benefits but violates any provisions of this Agreement, the PIIA or any other agreement entered into by the Employee and the Company after termination of employment, the Company will be entitled to immediately stop paying any further installments of the Base Separation Benefits.

(d) This Section 8 sets forth the only obligations of the Company with respect to the termination of the Employee's employment with the Company, except as otherwise required by law, and the Employee acknowledges that, upon the termination of the Employee's employment, the Employee shall not be entitled to any payments or benefits which are not explicitly provided in Section 8.

(e) Upon termination of the Employee's employment hereunder for any reason, the Employee shall be deemed to have resigned as director and/or officer of the Company and each subsidiary of the Company, to the extent applicable, effective as of the date of such termination, unless otherwise requested by the Board.

(f) The provisions of this Section 8 shall survive any termination of this Agreement.

9. Section 409A. The intent of the parties to this Agreement is that the payments, compensation and benefits under this Agreement be exempt from or comply with Section 409A of the Code and the regulations and guidance promulgated thereunder (collectively, "**Section 409A**") and, in this connection, the following shall be applicable:

(a) To the greatest extent possible, this Agreement shall be interpreted to be exempt from or in compliance with Section 409A.

(b) If any severance, compensation, or benefit required by this Agreement is to be paid in a series of installment payments, each individual payment in the series shall be considered a separate payment for purposes of Section 409A.

(c) If any severance, compensation, or benefit required by this Agreement that constitutes "nonqualified deferred compensation" within the meaning of Section 409A is considered to be paid on account of "separation from service" within the meaning of Section 409A, and the Employee is a "specified employee" within the meaning of Section 409A, no payments of any of such severance, compensation, or benefit shall be made until the earlier of six (6) months plus one (1) day after such separation from service or the Employee's death (the "**New Payment Date**"). The aggregate amount of any such payments that would have otherwise been paid during the period between the date of separation from service and the New Payment Date shall be paid to the Employee or his estate in a lump sum payment on the New Payment Date. Thereafter, any severance, compensation, or benefit required by this Agreement that remains outstanding as of the day immediately following the New Payment Date shall be paid without delay over the time period originally scheduled, in accordance with the terms of this Agreement.

(d) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Employee's termination of employment, then such payments or benefits shall be payable only upon the Employee's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A 1(h).

(e) The Company makes no representation or warranty and shall have no liability to the Employee or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

(f) The provisions of this Section 9 shall survive any termination of this Agreement.

10. Section 280G.

(a) Notwithstanding any other provision of this Agreement or any other plan, arrangement or agreement to the contrary, if any of the payments or benefits provided or to be provided by the Company or its affiliates to the Employee or for the Employee's benefit pursuant to the terms of this Agreement or otherwise ("**Covered Payments**") constitute parachute payments ("**Parachute Payments**") within the meaning of Section 280G of the Code and would, but for this Section 10 be subject to the excise tax imposed under Section 4999 of the Code (or any successor provision thereto) or any similar tax imposed by state or local law or any interest or penalties with respect to such taxes (collectively, the "**Excise Tax**"), then prior to making the Covered Payments, a calculation shall be made comparing (i) the Net Benefit (as defined below) to the Employee of the Covered Payments after payment of the Excise Tax to (ii) the Net Benefit to the Employee if the Covered Payments are limited to the extent necessary to avoid being subject to the Excise Tax. Only if the amount calculated under (i) above is less than the amount under (ii) above will the Covered Payments be reduced to the minimum extent necessary to ensure that no portion of the Covered Payments is subject to the Excise Tax (that amount, the "**Reduced Amount**"). "**Net Benefit**" shall mean the present value of the Covered Payments net of all federal, state, local, foreign income, employment and excise taxes.

(b) Any such reduction shall be made in accordance with Section 409A of the Code and the following: (i) the Covered Payments which do not constitute nonqualified deferred compensation subject to Section 409A of the Code shall be reduced first; and (ii) all other Covered Payments shall then be reduced as follows: (A) cash payments shall be reduced before non-cash payments; and (B) payments to be made on a later payment date shall be reduced before payments to be made on an earlier payment date.

(c) Any determination required under this Section 10 shall be made in writing in good faith by the accounting firm that was the Company's independent auditor immediately before the Change of Control (the "**Accounting Firm**"). The Accounting Firm shall provide detailed supporting calculations to the Company and the Employee as requested by the Company or the Employee. The Company and the Employee shall provide the Accounting Firm with such information and documents as the Accounting Firm may reasonably request in order to make a

determination under this Section 10. For purposes of making the calculations and determinations required by this Section 10, the Accounting Firm may rely on reasonable, good faith assumptions and approximations concerning the application of Section 280G and Section 4999 of the Code. The Accounting Firm's determinations shall be final and binding on the Company and the Employee. The Company shall be responsible for all fees and expenses incurred by the Accounting Firm in connection with the calculations required by this Section 10.

(d) It is possible that after the determinations and selections made pursuant to this Section 10 the Employee will receive Covered Payments that are in the aggregate more than the amount provided under this Section 10 ("**Overpayment**") or less than the amount provided under this Section 10 ("**Underpayment**").

(i) In the event that: (A) the Accounting Firm determines, based upon the assertion of a deficiency by the Internal Revenue Service against either the Company or the Employee which the Accounting Firm believes has a high probability of success, that an Overpayment has been made or (B) it is established pursuant to a final determination of a court or an Internal Revenue Service proceeding that has been finally and conclusively resolved that an Overpayment has been made, then the Employee shall pay any such Overpayment to the Company.

(ii) In the event that: (A) the Accounting Firm, based upon controlling precedent or substantial authority, determine that an Underpayment has occurred or (B) a court of competent jurisdiction determines that an Underpayment has occurred, any such Underpayment will be paid promptly by the Company to or for the benefit of the Employee.

11. Miscellaneous.

(a) This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the State of California, without giving effect to its principles of conflicts of laws.

(b) In the event of any dispute arising out of, or relating to, this Agreement or the breach thereof, or regarding the interpretation thereof, the parties agree to submit any differences to nonbinding mediation prior to pursuing resolution through the courts. The parties hereby submit to the exclusive jurisdiction of the state and federal courts situated in San Francisco County, California, and agree that service of process in such court proceedings shall be satisfactorily made upon each other if sent by registered mail addressed to the recipient at the address referred to in Section 11(g) below.

(c) This Agreement shall be binding upon and inure to the benefit of the parties hereto, and their respective heirs, legal representatives, successors and permitted assigns.

(d) This Agreement, and the Employee's rights and obligations hereunder, may not be assigned by the Employee. The rights and obligations of the Company under this Agreement shall inure to the benefit of and shall be binding upon the successors and assigns of the Company, including any successors or assigns in connection with any sale, transfer or other disposition of all or substantially all of its business or assets.

(e) This Agreement cannot be amended orally, or by any course of conduct or dealing, but only by a written agreement signed by the parties hereto.

(f) The failure of either party to insist upon the strict performance of any of the terms, conditions and provisions of this Agreement shall not be construed as a waiver or relinquishment of future compliance therewith, and such terms, conditions and provisions shall remain in full force and effect. No waiver of any term or condition of this Agreement on the part of either party shall be effective for any purpose whatsoever unless such waiver is in writing and signed by such party.

(g) All notices, requests, consents and other communications, required or permitted to be given hereunder, shall be in writing and shall be delivered personally or by an overnight courier service or sent by registered or certified mail, postage prepaid, return receipt requested, to the Employee at the last address of record in his personnel file and to the Company at the address for its corporate headquarters, and shall be deemed given when so delivered personally or by overnight courier, or, if mailed, five days after the date of deposit in the United States mail. Either party may designate another address, for receipt of notices hereunder by giving notice to the other party in accordance with this Section 11(g).

(h) This Agreement sets forth the entire agreement and understanding of the parties relating to the subject matter hereof, and supersedes all prior agreements, arrangements and understandings, written or oral, relating to the subject matter hereof, including the offer letter dated October 21, 2020 by and between the Company and Employee. No representation, promise or inducement has been made by either party that is not embodied in this Agreement, and neither party shall be bound by or liable for any alleged representation, promise or inducement not so set forth.

(i) As used in this Agreement, "affiliate" of a specified person or entity shall mean and include any person or entity controlling, controlled by or under common control with the specified person or entity.

(j) The section headings contained herein are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

(k) This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same original, binding document. Any facsimile, PDF reproduction of original signatures or other electronic transmission of a signed counterpart shall be deemed to be an original counterpart and any signature appearing thereon shall be deemed to be an original signature. Each party agrees that the electronic signatures of the parties included in this Agreement, including via DocuSign®, are intended to authenticate this writing and to have the same force and effect as manual signatures.

[*Remainder of Page Intentionally Left Blank – Signature Page Follows*]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement and intend it to be effective as of the Effective Date by proper person thereunto duly authorized.

ASSEMBLY BIOSCIENCES, INC.

By: /s/ John G. McHutchison, A.O., M.D.
Name: John G. McHutchison, A.O., M.D.
Title: Chief Executive Officer and President

EMPLOYEE

/s/ Nicole S. White, Ph.D.
Name: Nicole S. White, Ph.D.

Exhibit 21.1

Subsidiaries of Assembly Biosciences, Inc.

Subsidiaries	State or Other Jurisdiction of Incorporation or Organization
Assembly Pharmaceuticals, Inc.	Delaware
Assembly Biotechnology Development (Shanghai) Co, Ltd.	China
Assembly Biosciences Hong Kong Limited	Hong Kong
Assembly Biosciences Cayman	Cayman Islands

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-270760) of Assembly Biosciences, Inc.,

(2) Registration Statement (Form S-8 No. 333-173613) pertaining to the Ventrus Biosciences, Inc. 2007 Stock Incentive Plan and the Ventrus Biosciences, Inc. 2010 Equity Incentive Plan,

(3) Registration Statement (Form S-8 No. 333-182167) pertaining to the Ventrus Biosciences, Inc. 2010 Equity Incentive Plan,

(4) Registration Statement (Form S-8 No. 333-198803) pertaining to the Assembly Biosciences, Inc. 2014 Stock Incentive Plan,

(5) Registration Statement (Form S-8 No. 333-213019) pertaining to the Assembly Biosciences, Inc. Amended and Restated 2014 Stock Incentive Plan,

(6) Registration Statement (Form S-8 No. 333-216902) pertaining to certain Non-Qualified Stock Option Agreements dated May 16, 2014,

(7) Registration Statement (Form S-8 No. 333-219919) pertaining to the Assembly Biosciences, Inc. 2017 Inducement Award Plan,

(8) Registration Statement (Form S-8 No. 333-226703) pertaining to the Assembly Biosciences, Inc. 2018 Stock Incentive Plan and the Assembly Biosciences, Inc. 2018 Employee Stock Purchase Plan,

(9) Registration Statement (Form S-8 No. 333-233030) pertaining to the Assembly Biosciences, Inc. 2018 Stock Incentive Plan,

(10) Registration Statement (Form S-8 No. 333-234580) pertaining to the Assembly Biosciences, Inc. 2019 Inducement Award Plan and the Assembly Biosciences, Inc. Amended and Restated 2014 Stock Incentive Plan,

(11) Registration Statement (Form S-8 No. 333-248476) pertaining to the Assembly Biosciences, Inc. 2018 Stock Incentive Plan and the Assembly Biosciences, Inc. 2020 Inducement Award Plan,

(12) Registration Statement (Form S-8 No. 333-258516) pertaining to the Assembly Biosciences, Inc. 2018 Stock Incentive Plan and the Assembly Biosciences, Inc. Amended and Restated 2018 Employee Stock Purchase Plan,

(13) Registration Statement (Form S-8 No. 333-266711) pertaining to the Assembly Biosciences, Inc. 2018 Stock Incentive Plan,

(14) Registration Statement (Form S-8 No. 333-273836) pertaining to the Assembly Biosciences, Inc. 2018 Stock Incentive Plan and the Assembly Biosciences, Inc. Amended and Restated 2014 Stock Incentive Plan

of our report dated March 28, 2024, with respect to the consolidated financial statements of Assembly Biosciences, Inc. included in this Annual Report (Form 10-K) of Assembly Biosciences, Inc. for the year ended December 31, 2024.

/s/ Ernst & Young LLP

San Jose, California
March 28, 2024

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jason A. Okazaki, certify that:

(1) I have reviewed this annual report on Form 10-K for the year ended December 31, 2023 of Assembly Biosciences, Inc.;

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

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

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

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

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

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

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

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

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

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

Dated: March 28, 2024

/s/ Jason A. Okazaki

Jason A. Okazaki
Chief Executive Officer and President
(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

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

In connection with the annual report on Form 10-K of Assembly Biosciences, Inc. (the Company) for the fiscal year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Jason A. Okazaki, Chief Executive Officer and President (Principal Executive Officer and Principal Financial Officer) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Dated: March 28, 2024

/s/ Jason A. Okazaki

Jason A. Okazaki
Chief Executive Officer and President
(Principal Executive Officer and Principal Financial Officer)

Exhibit 97.1

CLAWBACK POLICY

The Board of Directors (the "Board") of Assembly Biosciences, Inc. (the "Company") believes that it is appropriate for the Company to adopt this Clawback Policy (the "Policy") to be applied to the Executive Officers of the Company and adopts this Policy to be effective as of the Effective Date.

1.Definitions

For purposes of this Policy, the following definitions shall apply:

a) "Committee" means the Compensation Committee of the Board.

b) "Company Group" means the Company and each of its Subsidiaries, as applicable.

c) "Covered Compensation" means any Incentive-Based Compensation granted, vested or paid to a person who served as an Executive Officer at any time during the performance period for the Incentive-Based Compensation and that was received (1) on or after the effective date of the Nasdaq listing standard, (2) after the person became an Executive Officer and (3) at a time that the Company had a class of securities listed on a national securities exchange or a national securities association.

d) "Effective Date" means October 2, 2023.

e) "Erroneously Awarded Compensation" means the amount of Covered Compensation granted, vested or paid to a person during the fiscal period when the applicable Financial Reporting Measure relating to such Covered Compensation was attained that exceeds the amount of Covered Compensation that otherwise would have been granted, vested or paid to the person had such amount been determined based on the applicable Restatement, computed without regard to any taxes paid (i.e., on a pre-tax basis). For Covered Compensation based on stock price or total stockholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Restatement, the Committee will determine the amount of such Covered Compensation that constitutes Erroneously Awarded Compensation, if any, based on a reasonable estimate of the effect of the Restatement on the stock price or total stockholder return upon which the Covered Compensation was granted, vested or paid and the Committee shall maintain documentation of such determination and provide such documentation to the Nasdaq.

f) "Exchange Act" means the Securities Exchange Act of 1934.

g) "Executive Officer" means each "officer" of the Company as defined under Rule 16a-1(f) under Section 16 of the Exchange Act, which shall be deemed to include any individuals identified by the Company as executive officers pursuant to Item 401(b) of Regulation S-K under the Exchange Act. Both current and former Executive Officers are subject to the Policy in accordance with its terms.

h) "Financial Reporting Measure" means (1) any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures and may consist of GAAP or non-GAAP financial measures (as defined under Regulation G of the Exchange Act and Item 10 of Regulation S-K under the Exchange Act), (2) stock price or (3) total stockholder return. Financial Reporting Measures may or may not be filed with the SEC and may be presented outside the Company's financial statements, such as in Managements' Discussion and Analysis of Financial Conditions and Result of Operations or in the performance graph required under Item 201(e) of Regulation S-K under the Exchange Act.

i) "Home Country" means the Company's jurisdiction of incorporation.

j) "Incentive-Based Compensation" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure. Incentive-Based Compensation is deemed "received" in the Company's fiscal period during which the Financial Reporting Measure specified in or otherwise relating to the Incentive-Based Compensation award is attained, even if the grant, vesting or payment of the Incentive-Based Compensation occurs after the end of that period.

k) "Lookback Period" means the three completed fiscal years (plus any transition period of less than nine months that is within or immediately following the three completed fiscal years and that results from a change in the Company's fiscal year) immediately preceding the date on which the Company is required to prepare a Restatement for a given reporting period, with such date being the earlier of: (1) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Restatement, or (2) the date a court, regulator or other legally authorized body directs the Company to prepare a Restatement. Recovery of any Erroneously Awarded Compensation under the Policy is not dependent on if or when the Restatement is actually filed.

l) "Nasdaq" means the Nasdaq Stock Market.

m) "Restatement" means a required accounting restatement of any Company financial statement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including (1) to correct an error in previously issued financial statements that is material to the previously issued financial statements (commonly referred to as a "Big R" restatement) or (2) to correct an error in previously issued financial statements that is not material to the previously issued financial statements but that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (commonly referred to as a "little r" restatement). Changes to the Company's financial statements that do not represent error corrections under the then-current relevant accounting standards will not constitute Restatements. Recovery of any Erroneously Awarded Compensation under the Policy is not dependent on fraud or misconduct by any person in connection with the Restatement.

n) "SEC" means the United States Securities and Exchange Commission.

o) "Subsidiary" means any domestic or foreign corporation, partnership, association, joint stock company, joint venture, trust or unincorporated organization "affiliated" with the Company, that is, directly or indirectly, through one or more intermediaries, "controlling", "controlled by" or "under

common control with", the Company. "Control" for this purpose means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of such person, whether through the ownership of voting securities, contract or otherwise.

2.Recoupment of Erroneously Awarded Compensation

In the event of a Restatement, any Erroneously Awarded Compensation received during the Lookback Period prior to the Restatement (a) that is then-outstanding but has not yet been paid shall be automatically and immediately forfeited and (b) that has been paid to any person shall be subject to reasonably prompt repayment to the Company Group in accordance with Section 3 of this Policy. The Committee must pursue (and shall not have the discretion to waive) the forfeiture and/or repayment of such Erroneously Awarded Compensation in accordance with Section 3 of this Policy, except as provided below.

Notwithstanding the foregoing, the Committee (or, if the Committee is not a committee of the Board responsible for the Company's executive compensation decisions and composed entirely of independent directors, a majority of the independent directors serving on the Board) may determine not to pursue the forfeiture and/or recovery of Erroneously Awarded Compensation from any person if the Committee determines that such forfeiture and/or recovery would be impracticable due to any of the following circumstances: (1) the direct expense paid to a third party (for example, reasonable legal expenses and consulting fees) to assist in enforcing the Policy would exceed the amount to be recovered (following reasonable attempts by the Company Group to recover such Erroneously Awarded Compensation, the documentation of such attempts, and the provision of such documentation to the Nasdaq), (2) pursuing such recovery would violate the Company's Home Country laws adopted prior to November 28, 2022 (provided that the Company obtains an opinion of Home Country counsel acceptable to the Nasdaq that recovery would result in such a violation and provides such opinion to the Nasdaq), or (3) recovery would likely cause any otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of Company Group, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

3.Means of Repayment

In the event that the Committee determines that any person shall repay any Erroneously Awarded Compensation, the Committee shall provide written notice to such person by email or certified mail to the physical address on file with the Company Group for such person, and the person shall satisfy such repayment in a manner and on such terms as required by the Committee, and the Company Group shall be entitled to set off the repayment amount against any amount owed to the person by the Company Group, to require the forfeiture of any award granted by the Company Group to the person, or to take any and all necessary actions to reasonably promptly recoup the repayment amount from the person, in each case, to the fullest extent permitted under applicable law, including without limitation, Section 409A of the Internal Revenue Code and the regulations and guidance thereunder. If the Committee does not specify a repayment timing in the written notice described above, the applicable person shall be required to repay the Erroneously Awarded Compensation to the Company Group by wire, cash or cashier's check no later than thirty (30) days after receipt of such notice.

4.No Indemnification

No person shall be indemnified, insured or reimbursed by the Company Group in respect of any loss of compensation by such person in accordance with this Policy, nor shall any person receive any advancement of expenses for disputes related to any loss of compensation by such person in accordance with this Policy, and no person shall be paid or reimbursed by the Company Group for any premiums paid by such person for any

third-party insurance policy covering potential recovery obligations under this Policy. For this purpose, "indemnification" includes any modification to current compensation arrangements or other means that would amount to *de facto* indemnification (for example, providing the person a new cash award which would be cancelled to effect the recovery of any Erroneously Awarded Compensation). In no event shall the Company Group be required to award any person an additional payment if any Restatement would result in a higher incentive compensation payment.

5.Miscellaneous

This Policy generally will be administered and interpreted by the Committee. Any determination by the Committee with respect to this Policy shall be final, conclusive and binding on all interested parties. Any discretionary determinations of the Committee under this Policy, if any, need not be uniform with respect to all persons, and may be made selectively amongst persons, whether or not such persons are similarly situated.

This Policy is intended to satisfy the requirements of Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, as it may be amended from time to time, and any related rules or regulations promulgated by the SEC or the Nasdaq, including any additional or new requirements that become effective after the Effective Date which upon effectiveness shall be deemed to automatically amend this Policy to the extent necessary to comply with such additional or new requirements.

The provisions in this Policy are intended to be applied to the fullest extent of the law. To the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to applicable law. The invalidity or unenforceability of any provision of this Policy shall not affect the validity or enforceability of any other provision of this Policy. Recoupment of Erroneously Awarded Compensation under this Policy is not dependent upon the Company Group satisfying any conditions in this Policy, including any requirements to provide applicable documentation to Nasdaq.

The rights of the Company Group under this Policy to seek forfeiture or reimbursement are in addition to, and not in lieu of, any rights of recoupment, or remedies or rights other than recoupment, that may be available to the Company Group pursuant to the terms of any law, government regulation or stock exchange listing requirement or any other policy, code of conduct, employee handbook, employment agreement, equity award agreement, or other plan or agreement of the Company Group.

6.Amendment and Termination

To the extent permitted by, and in a manner consistent with applicable law, including SEC and Nasdaq rules, the Committee may terminate, suspend or amend this Policy at any time in its discretion.

7.Successors

This Policy shall be binding and enforceable against all persons and their respective beneficiaries, heirs, executors, administrators or other legal representatives with respect to any Covered Compensation granted, vested or paid to or administered by such persons or entities.

Approved by the Compensation Committee: September 12, 2023

Adopted by the Board of Directors: September 13, 2023

ASSEMBLY BIOSCIENCES, INC.

CLAWBACK POLICY

ACKNOWLEDGMENT, CONSENT AND AGREEMENT

I acknowledge that I have received and reviewed a copy of the Assembly Biosciences, Inc. Clawback Policy (as may be amended from time to time, the "Policy") and I have been given an opportunity to ask questions about the Policy and review it with my counsel. I knowingly, voluntarily and irrevocably consent to and agree to be bound by and subject to the Policy's terms and conditions, including that I will return any Erroneously Awarded Compensation that is required to be repaid in accordance with the Policy. I further acknowledge, understand and agree that (1) the compensation that I receive, have received or may become entitled to receive from the Company Group is subject to the Policy, and the Policy may affect such compensation and (2) I have no right to indemnification, insurance payments or other reimbursement by or from the Company Group for any compensation that is subject to recoupment and/or forfeiture under the Policy. Capitalized terms not defined herein have the meanings set forth in the Policy.

Signed: _____

Print Name: _____

Date: _____