UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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: 001-41365

HILLEVAX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**85-0545060**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
321 Harrison Avenue, Boston, Massachusetts	**02118**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 213-5054

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	HLVX	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 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

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

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

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

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

As of June 30, 2023, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $258.0 million based on the closing price of the registrant's common stock on the Nasdaq Global Select Market of $17.19 per share.

The number of shares of registrant's Common Stock outstanding as of March 11, 2024 was 49,700,828.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement (the Proxy Statement) for its 2024 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

HILLEVAX, INC.
Annual Report on Form 10-K
For the Fiscal Year Ended December 31, 2023

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Forward-Looking Statements and Market Data

This annual report on Form 10-K (Annual Report) contains forward-looking statements within the meaning of 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). All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing, costs, design and conduct of our ongoing and planned preclinical studies and clinical trials for our product candidates, the timing and likelihood of regulatory filings and approvals for our product candidates, our ability to commercialize our product candidates, if approved, plans and objectives of management for future operations and future results of anticipated product development efforts, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. This Annual Report also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “continue” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target” or “will” or the negative of these terms or other similar expressions. These forward-looking statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions, including, without limitation, the risk factors described in Part I, Item 1A, “Risk Factors” of this Annual Report. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

This Annual Report includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this Annual Report appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and tradenames.

We maintain a website at www.hillevax.com, to which we regularly post copies of our press releases as well as additional information about us. Our filings with the Securities and Exchange Commission (SEC) are available free of charge through our website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. Information contained in our website does not constitute a part of this report or our other filings with the SEC.

PART I

Item 1. Business

Our founders and inspirations

We are founded on the legacies of leading vaccine developers who inspire us to build a company to benefit human health on a global scale. Our late co-founder, Dr. Tadataka “Tachi” Yamada, championed vaccines as a powerful means to address health inequities and equalize opportunity for people around the world. As the former Chief Medical and Scientific Officer at Takeda Pharmaceutical Company Limited (Takeda Pharmaceuticals), Tachi helped establish Takeda Pharmaceuticals’ vaccine pipeline, which included the most advanced norovirus vaccine candidate in clinical development. Through his most recent role as a venture partner at Frazier Healthcare Partners (Frazier), he helped Frazier and Takeda Pharmaceuticals launch their third collaboration, HilleVax, to continue the development of this novel norovirus vaccine candidate, HIL-214 (formerly TAK-214). At HilleVax, we aim to continue Tachi’s mission of improving global health with a sense of urgency by always putting patients first.

Our work, and company name itself, is also inspired by Dr. Maurice Hilleman. Dr. Hilleman is considered by many to be the father of modern vaccines. He developed many of the vaccines that are routinely recommended for children today. By the end of his career, Dr. Hilleman had played a key role in developing more than forty vaccines, including those for the flu, chickenpox, hepatitis A, hepatitis B, pneumococcus, meningococcus, measles, mumps, rubella, and other diseases. These vaccines are estimated to save millions of lives every year. We are honored that his daughter, Jeri Hilleman, serves on our Board of Directors.

We aim to have a global impact on human health and believe the best way to achieve this goal is by developing novel vaccines for severe and life-threatening diseases. HIL-214 is our foundational vaccine candidate from which we are building our company. We are honored to continue Dr. Yamada’s and Dr. Hilleman’s legacies through the further development of HIL-214 and other potential vaccine candidates.

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines. Our most advanced program, HIL-214, is a virus-like particle (VLP) based vaccine candidate for the prevention of moderate-to-severe acute gastroenteritis (AGE) caused by norovirus infection. It is estimated that norovirus causes nearly 700 million cases of illness and more than 200,000 deaths worldwide per year, as well as significant additional economic and social burden. To date, HIL-214 has been studied in nine clinical trials conducted by Takeda Vaccines, Inc. (Takeda) and its predecessor, LigoCyte Pharmaceuticals, Inc. (LigoCyte), which collectively generated safety data from more than 4,500 subjects and immunogenicity data from more than 2,200 subjects, including safety and immunogenicity data from more than 800 pediatric subjects. A randomized, placebo-controlled Phase 2b field efficacy trial enrolled 4,712 adult subjects, and HIL-214 was well tolerated and demonstrated clinical proof of concept in preventing moderate-to-severe cases of AGE from norovirus infection. In September 2021, an open investigational new drug application (IND) was transferred to us from Takeda, under which we initiated a Phase 2b clinical trial, NEST-IN1 (Norovirus Efficacy and Safety Trial in Infants, or NOR-212), in May 2022 to evaluate the safety, immunogenicity, and efficacy of HIL-214 in infants. In May 2022, we completed enrollment of the prespecified 200 subject run-in for NEST-IN1. We resumed enrollment in NEST-IN1 in August 2022, following the prespecified safety assessment by the clinical trial's data monitoring committee. In December 2022, we reported positive interim immunogenicity results for the first 200 subjects of NEST-IN1. We completed enrollment for NEST-IN1 in April 2023. We expect to report top-line safety and clinical efficacy data in mid-2024. We believe HIL-214 has the potential to be the first ever vaccine approved for norovirus-related illness and, if approved, will help grow HilleVax into a leading global vaccines company.

Norovirus is the most common cause of viral AGE worldwide and is characterized by diarrhea, vomiting, abdominal pain, nausea, and, sometimes, fever that may lead to clinically significant dehydration. The global cost of norovirus-caused AGE is estimated to be over $4 billion in direct health system costs and approximately $60 billion in societal costs per year. In the United States alone, norovirus-caused AGE is estimated to result in $2 billion in direct medical costs and $10 billion in societal costs per year. While norovirus can cause illness in any age group, the majority of deaths and illnesses due to norovirus are borne by young children and older adults. In children younger than four years of age, norovirus is estimated to cause 95,000 deaths and 450 million illnesses globally each year. Almost all children will experience at least one norovirus infection by the age of five. In the United States, this results in approximately 627,000 outpatient visits, 281,000 emergency room visits and 14,000 hospitalizations each year for children under the age of five. Older adults are also vulnerable to severe norovirus infection given their higher rate of comorbidities, especially if they live in settings conducive to outbreaks, such as assisted living facilities. For adults older than 55 years of age, norovirus is estimated to cause 78,000 deaths and 81 million illnesses globally each year. In the United States, older adults are estimated to

account for 17% of illnesses due to norovirus yet comprise 52% of hospitalizations and 94% of deaths. There are currently no approved vaccines or antiviral therapies for either the prevention or treatment of norovirus-related illness.

In July 2021, Takeda granted us, among other things, an exclusive license (the Takeda License) under certain intellectual property to develop and commercialize HIL-214 (formerly TAK-214) worldwide (excluding Japan) in exchange for upfront consideration as well as future cash milestones and royalties on net sales. Takeda will retain commercialization rights in Japan, and we will integrate certain Japan development activities into our global development plan. As of March 1, 2024, our intellectual property portfolio for HIL-214 includes 25 issued U.S. patents, including eight issued U.S. composition and formulation patents covering HIL-214 and components thereof, all of which are licensed to us under the Takeda License.

HIL-214 is a bivalent (containing two proteins) vaccine candidate consisting of VLPs representing two common genotypes of norovirus and is co-formulated with an aluminum hydroxide (alum) adjuvant, which is commonly used in adult and pediatric vaccines to enhance immunogenicity. Alum may also improve the stability of VLPs in solution. VLPs are self-assembling structures that mimic the unique and repetitive geometric features that characterize the surface of a live virus. VLPs can be produced in a wide range of expression systems and can be readily manufactured at large scale. Importantly, VLPs lack a viral genome and can therefore neither replicate nor cause infection, which may present an important safety advantage over live vaccines. The genotypes represented by the two VLPs in HIL-214 are from the GI and GII genogroups of norovirus, which are responsible for the majority of human norovirus infection. VLP-based vaccines are well-characterized and include currently marketed vaccines, such as Gardasil, Cervarix, and Sci-B-Vac, and have been administered to millions of patients worldwide.

HIL-214 has been extensively evaluated in nine Phase 1 and 2 clinical trials conducted by Takeda. Safety data generated across more than 4,500 subjects in these trials showed that HIL-214 was well tolerated across all age groups and had an adverse event (AE) profile similar to that of other approved alum-adjuvanted vaccines. In infants between six weeks and six months of age who received two doses of HIL-214, AEs were largely mild to moderate in intensity, with the most common reactions being fussiness (19-28%), drowsiness (16-21%), diarrhea (10-19%), and pain near the injection site (9-21%) in 180 subjects studied. In adults, systemic AEs were found to occur at a rate similar to placebo, with the most common local reaction being pain near the injection site (48% for HIL-214 vs. 38% for placebo) in a safety subset of 377 subjects. In addition, immunogenicity data has been collected in over 2,200 subjects. HIL-214 was found to induce antibody responses greater than eight-fold above baseline at least 28 days post vaccination against norovirus in all age groups. An extensive set of clinical dose finding and formulation studies were conducted to evaluate the immune response across age groups and between the two VLPs contained in HIL-214. In a clinical trial of military recruits, in which 4,712 subjects were administered HIL-214 or placebo, HIL-214 demonstrated an estimated 80% efficacy in preventing AGE caused by norovirus strains represented in our vaccine candidate and 62% efficacy for AGE caused by any norovirus strain (including those not represented in HIL-214) in the first 45 days post vaccination. We believe this trial demonstrated clinical proof of concept and protection against strains not included in the vaccine (i.e., heterotypic, or cross-protection).

Our near-term clinical development plan is focused on infants, a population in which norovirus is routinely circulating and infections are common. We initiated a Phase 2b clinical trial, NEST-IN1, in May 2022 to evaluate the safety, immunogenicity, and efficacy of HIL-214 in infants. In May 2022, we completed enrollment of the prespecified 200 subject run-in for NEST-IN1. We resumed enrollment in NEST-IN1 in August 2022, following the prespecified safety assessment by the clinical trial's data monitoring committee. In December 2022, we reported positive interim immunogenicity results for the first 200 subjects of NEST-IN1. We completed enrollment for NEST-IN1 in April 2023. We expect to report top-line safety and clinical efficacy data for this trial in mid-2024. While Takeda previously conducted both Phase 1 and 2 clinical trials of HIL-214, we have not previously completed any clinical trials. Based on the results from NEST-IN1, if positive, we plan to proceed to a pivotal Phase 3 efficacy trial in infants. We expect that the Phase 3 trial will enroll approximately 7,000 to 12,000 subjects that will be randomized 1:1 into the vaccine or control arm. We believe that successful completion of these Phase 2b and Phase 3 trials, together with existing clinical data and additional co-administration trials with other common pediatric vaccines and lot-to-lot consistency trials, will support regulatory submissions for marketing approval in the United States, Europe, Japan, and other key markets. We also expect these data to be evaluated by the Advisory Committee on Immunization Practices (ACIP), an advisory body of the Centers for Disease Control and Prevention (CDC) which develops vaccine recommendations for children and adults in the United States. New pediatric vaccines that receive a preferred recommendation from ACIP are historically widely adopted in the United States, with many reaching national immunization rates of over 90%. In addition, depending upon the results from our Phase 2b trial in infants, we also plan to initiate a series of trials to support the potential approval of HIL-214 for older children, adults, and older adults.

The global vaccine market was estimated to be over $140 billion in 2021. While there are currently no approved vaccines for the prevention of norovirus-related illness, we believe there are market analogues that we can use to estimate the size of the commercial opportunity for HIL-214. In the pediatric market, we believe that rotavirus vaccines are the closest analogue to HIL-214. Rotavirus was the leading cause of pediatric viral AGE before the introduction of the rotavirus

vaccines, Rotarix and RotaTeq. These vaccines, approved only in infants, are now widely adopted worldwide, with many countries achieving vaccination rates above 80% among one-year-olds. Rotavirus vaccines generated approximately $1.6 billion in global sales in 2023. In the older adult market, we believe that Shingrix, a vaccine developed by GlaxoSmithKline to prevent shingles, and the newly launched RSV vaccines are analogues for HIL-214 due to the similarities in morbidity, mortality and economic burden between shingles, RSV, and norovirus each before the introduction of a vaccine. Shingrix generated $4.4 billion in sales in 2023. The RSVs Arexvy and Abrysvo, developed by GlaxosSmithKline and Pfizer, respectively, generated an aggregate of $1.2 billion in sales in the third quarter of 2023. Furthermore, we believe that there is a commercial opportunity in other groups at high risk for norovirus infection, such as healthcare workers, immunocompromised individuals, military personnel, food handlers, and travelers, including cruise ship passengers.

Our pipeline

The following chart summarizes our current development programs.

1. *All previously completed trials to date conducted by Takeda and Ligocyte.*
2. *Completed Phase 2 trial(s) evaluated safety, immunogenicity, and dose/regimen.*
3. *Clinical trials conducted to date have been in children up to 9 years of age; however, we plan to seek licensure in a broader target population of children 2 to 17 years of age.*
4. *Completed Phase 2b trial evaluating field efficacy.*

In addition, in January 2024 we in-licensed rights to HIL-216, a hexavalent VLP vaccine candidate for norovirus that includes six common norovirus genotypes, GI.1, GII.2, GII.3, GII.4, GII.6 and GII.17. The IND for HIL-216 was cleared by the FDA in September 2023. We plan to initiate a Phase 1 clinical trial of HIL-216 in late 2024.

Our strategy

Our goal is to be a leader in the development and commercialization of novel vaccines. Our strategy is initially focused on the development and commercialization of HIL-214 as the first potential vaccine for the prevention of AGE caused by norovirus infection. Key elements of this strategy include:

- **Advance the clinical development of HIL-214 for the prevention of norovirus-caused AGE in infants.** We are leveraging the extensive clinical data as well as our management team's vaccine development experience to advance HIL-214 through Phase 2b and 3 clinical trials in infants. We believe that initial development of HIL-214 in infants will de-risk its advancement given the endemic nature of disease in this population, which allows for rapid case accrual, and the lack of pre-existing immunity to norovirus, which may enhance the ability to show the effect of a vaccine. We initiated a Phase 2b clinical trial, NEST-IN1, in May 2022 to evaluate the safety, immunogenicity, and efficacy of HIL-214 in infants. In May 2022, we completed enrollment of the prespecified 200 subject run-in for NEST-IN1. We resumed enrollment in NEST-IN1 in August 2022, following the prespecified safety assessment by the clinical trial's data monitoring committee. In December 2022, we reported positive interim immunogenicity results for the first 200 subjects of NEST-IN1. We expect to report top-line safety and clinical efficacy data for this trial in mid-2024. Pending successful top-line data from the ongoing NEST-IN1 trial in infants, we plan to proceed to a pivotal Phase 3 efficacy trial in infants.
- **Expand the development of HIL-214 to older populations and other high-risk groups.** Given the vulnerability of older adults to norovirus infection, we plan to expand the development of HIL-214 to adults older than 60 years of age. We also plan to expand the development of HIL-214 to older children and adults to cover other high-risk populations such as healthcare workers, immunocompromised individuals, military personnel, food handlers, and travelers, including cruise ship passengers.

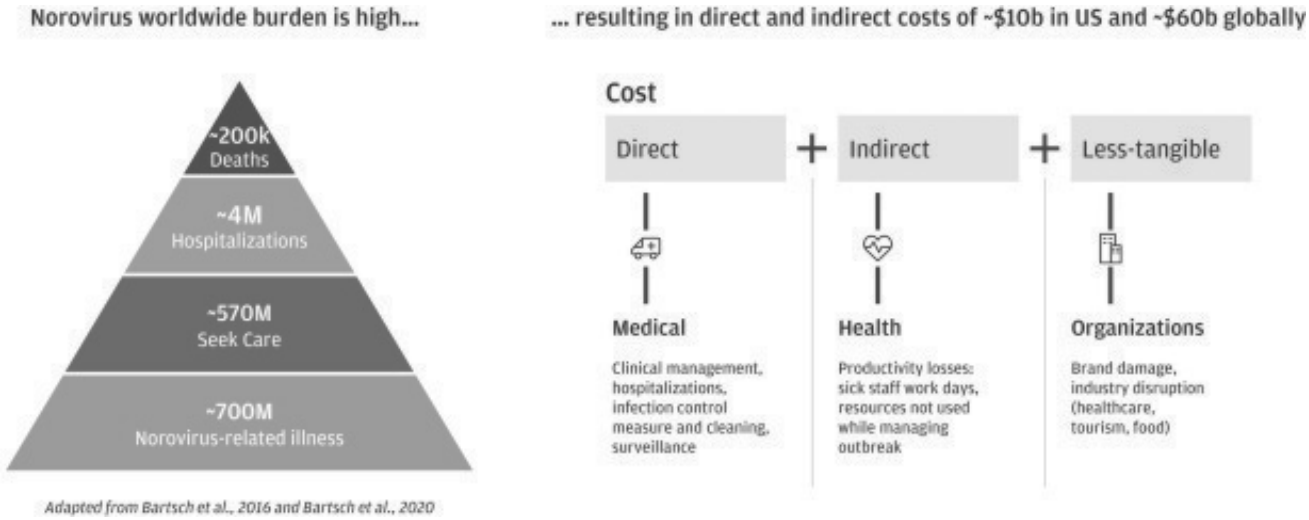
- **Commercialize HIL-214 in the United States.** We plan to independently commercialize HIL-214, if approved, in the United States by building a highly-targeted sales force to support the adoption of HIL-214. We also plan to seek a preferred recommendation from ACIP to facilitate the broad uptake of HIL-214.
- **Seek commercial partnerships to maximize the HIL-214 opportunity outside of the United States.** We believe there is a significant global commercial opportunity for HIL-214. To address geographies outside of the United States, we plan to seek one or more partners with existing commercial infrastructure and expertise in these markets.
- **Pursue next generation norovirus vaccine candidate with in-license of HIL-216.** We have in-licensed a hexavalent VLP norovirus vaccine candidate (HIL-216) from Chengdu Kanghua Biological Products Co., Ltd. (Kangh), a Chinese company. Our license provides world-wide rights to the vaccine outside of the Chinese market. We plan to develop HIL-216 as a potential next-generation, higher valency, VLP-based norovirus vaccine. We also plan to support alternative formulations or combinations where there is clear unmet need, clinical rationale, and commercial justification.
- **In-license or acquire additional products or technology platforms relevant to the prevention of other infectious diseases.** We intend to take advantage of our management team's vaccine expertise and extensive business development experience to opportunistically in-license or acquire additional innovative vaccines or technology platforms, such as our in-license of HIL-216.

Overview of norovirus

Overview

Norovirus is the most common cause of viral AGE. AGE is characterized by acute-onset vomiting and diarrhea, typically lasting between one and three days, that may be accompanied by abdominal cramps, nausea, and fever. Most infections result in a full recovery, although severe outcomes such as hospitalization and death are more common among young children and older adults. Given that there are no antiviral therapies available to treat norovirus infections, clinical management is focused on supportive care to prevent dehydration and manage symptoms.

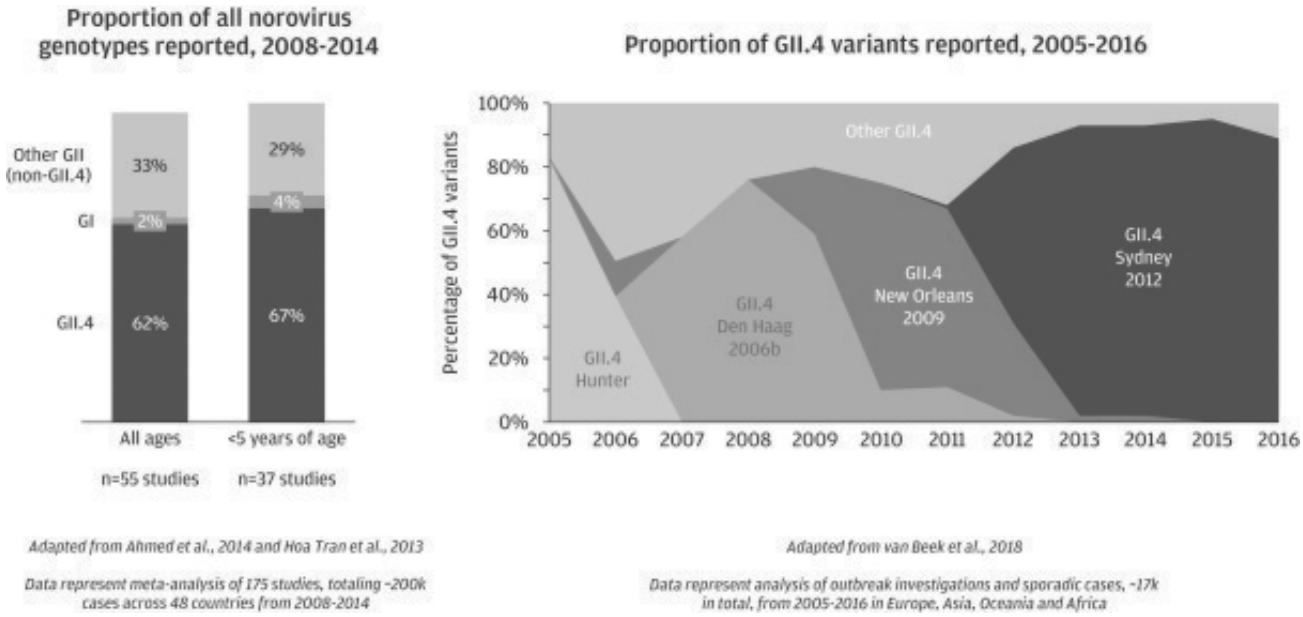
The burden of norovirus falls disproportionately on young children and older adults. Incidence of norovirus is highest among young children, with 70% of cases in children under four years of age occurring between six months and two years of age. As a result, almost all children will have experienced at least one norovirus infection by the age of five. While incidence is lower among older adults, norovirus illnesses are more likely to result in lingering symptoms, hospitalization, and death in this population. Older adults are also more likely to be found in high risk settings for norovirus outbreaks, such as long-term care facilities and hospitals. Other high-risk groups for norovirus infection include healthcare workers, immuno-compromised individuals, military personnel, food handlers, and travelers, including cruise ship passengers. Globally, norovirus is estimated to result in over approximately 700 million cases of AGE and 200,000 deaths per year, resulting in over $4 billion in direct health system costs and $60 billion in societal costs per year. In the United States alone, norovirus is estimated to result in over 20 million cases of AGE, resulting in over $2 billion in direct medical costs, and $10 billion in indirect societal costs, per year. In addition, outbreaks of norovirus at restaurant chains, cruise ships, and in other industries have caused significant industry disruptions and reputational damage to the affected brands.



Genogroups and genotypes

Noroviruses are a group of small, non-enveloped viruses belonging to the Caliciviridae family. Noroviruses contain a single-stranded positive-sense RNA genome that codes for seven nonstructural and two structural proteins. The first structural protein, VP1, encodes the major capsid protein. VP1 is further subdivided into the N-terminal, shell, and protruding domains. The protruding domain of VP1 is present on the surface of viral particles and is necessary for binding to HBGAs on epithelial cells in the human gastrointestinal tract.

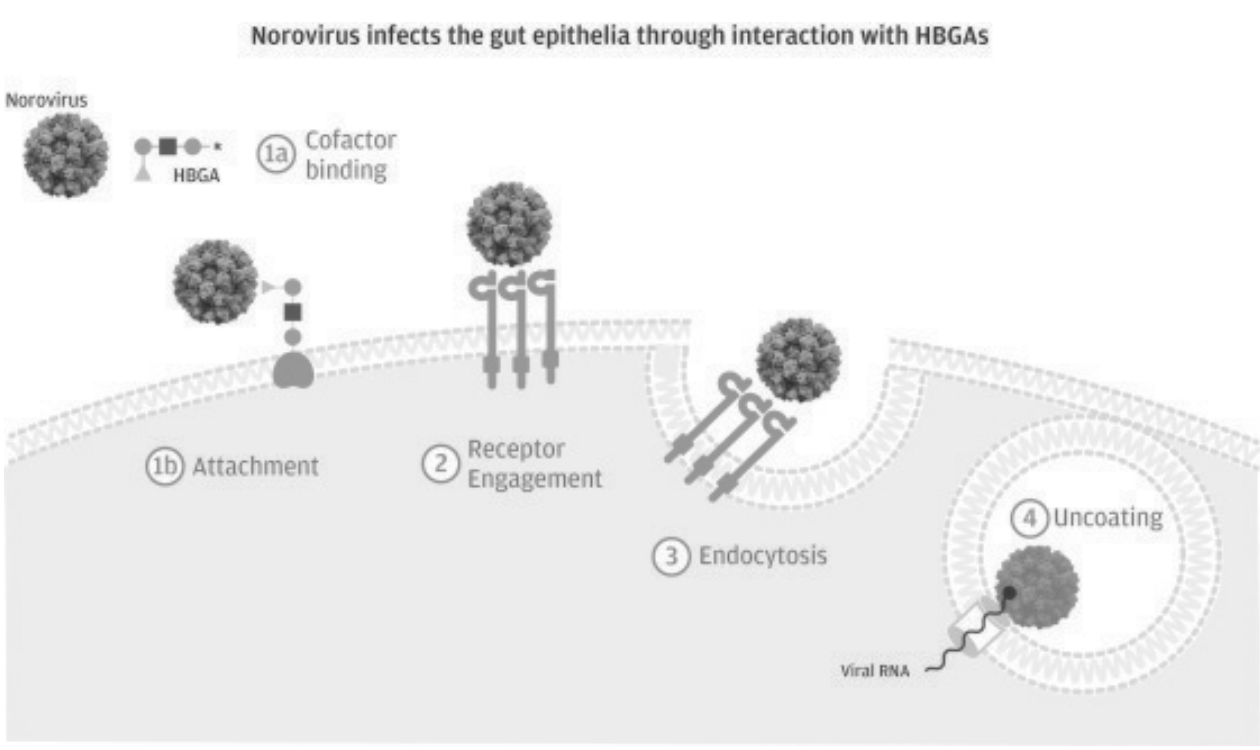
Noroviruses are classified into ten genetic groups called genogroups. These genogroups, GI through GX, are based on amino acid diversity in the major capsid protein VP1. Genogroups GI and GII are responsible for the majority of human infections across major geographies worldwide, with GII accounting for an estimated 96% of global prevalence. Norovirus genogroups are further subdivided into at least 48 genotypes: 9 genotypes in GI, 26 genotypes in GII, and 13 genotypes in GIII through GX. A single genotype, GII.4, is estimated to be responsible for nearly two-thirds of norovirus outbreaks in both developed and developing countries. GII.4 has been the dominant genotype in circulation for the last two decades, and of the GII.4 strains, GII.4 Sydney 2012 has been the predominant variant detected worldwide since 2012. In addition to causing the majority of norovirus infections, hospitalizations and deaths were more likely in outbreaks associated with GII.4 viruses.



Norovirus attachment and entry

Norovirus entry into host cells is a multi-step process. The first step is norovirus binding to attachment factors that concentrate the virus on the cell surface. The most well-characterized attachment factors are HBGAs. HBGAs are units of simple sugar that are bonded together, or oligosaccharides, found on the epithelia of the respiratory, genitourinary, and digestive tracts, as well as in body fluids such as blood and saliva. The interaction between norovirus and HBGAs is known to promote viral entry into host cells, and this interaction is supported by population genetics. Specifically, individuals with mutations in the FUT2 gene, which is required for secretion of HBGAs, are highly resistant to infection by GI.1 and most GII.4 norovirus strains. Approximately 20% of Caucasians lack a functional FUT2 gene. Given the importance of HBGAs for norovirus attachment and cell entry, measurement of HBGA-blocking antibodies is the primary functional method used to assess the immunogenicity of norovirus vaccine candidates. We believe that data from our ongoing and planned clinical trials of HIL-214 will help determine whether anti-HBGA antibodies are an appropriate surrogate for evaluating norovirus vaccine efficacy.

The next step for norovirus entry is receptor engagement. Receptors are essential host factors that bind to the norovirus particle and actively promote entry into the cell. The receptor(s) for human norovirus are currently unknown. The last steps for norovirus entry are cell entry, or endocytosis, and uncoating, which results in release of the viral genome into the host cytoplasm. New norovirus particles are then produced and released via cell lysis, which results in inflammation of the stomach or intestines, the underlying pathology of AGE.



Clinical presentation and management

Clinical presentation of norovirus infections can range widely, from asymptomatic infections to life-threatening dehydration and diarrhea. Asymptomatic cases are estimated to account for 30% of norovirus infections. For a symptomatic case, the illness typically begins after an incubation period of 12 to 48 hours and is characterized by acute-onset vomiting and diarrhea that may be accompanied by abdominal cramps, nausea, and fever. Other symptoms, including muscle pain, malaise, headache, and chills, can also occur. The duration of clinical symptoms is typically 12 to 72 hours in otherwise healthy individuals. The most serious complication is severe dehydration leading to hypovolemic shock, which occurs when the body loses more than one-fifth of its fluid supply. Hypovolemic shock makes it difficult for the heart to pump sufficient blood to the body and can lead to organ failure, coma, and death. Severe outcomes of acute AGE as a result of norovirus infection, such as hospitalization and death, are more likely among young children, older adults, and immunocompromised patients.

There are currently no antiviral therapies available to treat norovirus infection. Clinical management is focused on supportive therapy to prevent dehydration. First line therapy is comprised of oral rehydration solutions, followed by intravenous rehydration for patients with profuse vomiting or worsening dehydration that could lead to hypovolemic shock. Medicines to relieve pain, nausea, or vomiting can also be used.

Transmission and prevention

Norovirus is highly transmissible, with as few as 18 viral particles needed to make a person sick. For context, a single gram of feces can contain up to 95 billion particles of norovirus. A systematic review of norovirus outbreak data in the United States from 2009-2017 reported a median R0 (a measure of the average number of people who will contract a viral disease from one infected person) of 2.75, but this number is likely to be a lower bound for norovirus globally given generally high sanitation rates and comparatively easy access to clean food and water in the United States compared to other nations with higher burden of norovirus infection. For context, seasonal strains of influenza in the United States tend to have R0 values between 1 and 2.

There are three general modes of norovirus transmission: person-to-person, foodborne, and waterborne. Person-to-person transmission occurs mainly through the fecal-oral route and potentially through aerosolized vomitus. Viral shedding in stool can also occur before the onset of symptoms and continue up to eight weeks after a person has been infected, leading to secondary transmission rates, defined as the probability that some or all family members also become infected, of up to 30%. Person-to-person transmission can also occur indirectly through contaminated fomites, such as clothes and utensils, or through environmental surfaces. Foodborne transmission typically occurs by exposure to infected food handlers, although exposure to human waste further upstream in the food distribution system is also a possibility. For example, oysters filter ocean water through their bodies to get food and will absorb viral particulates when exposed to untreated human waste, which can make its way into ocean water in the case of leaky septic systems and/or

dysfunctional waste-water treatment plants. Waterborne transmission can occur through the failure to properly chlorinate municipal water or through the contamination of well water with human waste. Norovirus outbreaks can occur throughout the year, although increased activity is observed in the winter months.

Preventing the spread of norovirus is challenging. The virus can persist on environmental surfaces such as utensils and countertops for up to two weeks. Norovirus can remain infectious on foods that are frozen and until heated above 140°F. Furthermore, alcohol-based hand sanitizers are not as effective at removing norovirus particles as washing hands with soap and water, and their use in place of hand washing is associated with a greater risk for norovirus outbreaks in long-term care facilities. This resistance to common disinfectants appears to be unique to norovirus, as there have not been similar reports of outbreaks associated with the use of hand sanitizers in lieu of handwashing for other common viruses. The CDC recommends four strategies to help prevent the transmission of norovirus: proper hand hygiene, safe food handling, isolation while sick, and surface decontamination. Hand hygiene with running water and soap is viewed as the most effective method to control norovirus transmission. Fruit and vegetables should be carefully washed before eating, and affected individuals should refrain from preparing food for others for up to two days after symptoms stop. Furthermore, kitchen surfaces and frequently touched objects should be sanitized using chlorine-based disinfectants such as bleach. In the event of an outbreak in a high transmission environment like a cruise ship, nursing home, daycare, or hospital ward, a full decontamination procedure must be performed in order minimize the risk of additional spread.

Burden in young children

Norovirus routinely circulates among young children, a mode of transmission categorized as endemic. Although norovirus can infect all age groups, the incidence of norovirus is highest among young children. The GII genogroup is the dominant source of infection in children, accounting for 96% of all sporadic infections, and the GII.4 genotype, in particular, accounts for 70% of detected genotypes. The consistent dominance of GII.4 in circulation over more than two decades, particularly among children, highlights the importance of vaccination efforts to be directed against this strain.

Most infections are completely resolved, resulting in a full recovery, although severe outcomes such as hospitalization and death are more common among young children when considering global burden. In both high- and middle-income countries with mature rotavirus vaccination programs, norovirus is now the most common cause of pediatric gastroenteritis requiring medical care. In the United States, norovirus is estimated to result in 627,000 outpatient visits, 281,000 emergency room visits, and 14,000 hospitalizations each year for children under the age of five. Globally, norovirus is estimated to result in 450 million illnesses and 95,000 deaths annually for children under the age of four, resulting in a total societal cost of approximately $39 billion. In the United States alone, norovirus is estimated to result in 2.8 million illnesses annually in children under the age of four, resulting in a total societal cost of approximately $1.2 billion.

For comparison, norovirus today has a similar morbidity, mortality, and economic burden in children as rotavirus did before the introduction of rotavirus vaccines. Prior to rotavirus vaccines becoming available, rotavirus was estimated to result in 2.7 million illnesses each year in children under the age of five in the United States, resulting in a total societal cost of approximately $1.5 billion. Today, rotavirus vaccines are estimated to avert 280,000 outpatient visits, 62,000 emergency room visits, and 45,000 hospitalizations each year in the United States. When considering all age groups, the overall burden of norovirus is greater than that of rotavirus.

Further, norovirus today has a greater morbidity, mortality, and economic burden than shingles did before the introduction of shingles vaccines. Prior to shingles vaccines becoming available, shingles was estimated to result in 1 million illnesses, 46,000 hospitalizations, and 80 deaths each year among adults over 50 years of age in the United States, for a total societal cost of $2.4 billion. In comparison, norovirus results in 22 million illnesses, 96,000 hospitalizations, and 1,350 deaths each year among all age groups in the United States, for a total societal cost of $10 billion.

Comparison of norovirus burden (today) to rotavirus, shingles, and RSV burden (pre-vaccines) in the United States

Disease	Age	US cases	US hospitalizations	US deaths	US economic burden[1]
Norovirus	≤ 4 years	2.8 million	12,000	20	$1.2 billion
	5 – 64 years	15.7 million	34,000	70	$6.4 billion
	≥ 65 years	3.7 million	50,000	1,250	$3.2 billion
	All ages	22 million	96,000	1,350	$10 billion
Rotavirus (pre-vaccine)	≤ 5 years	2.7 million	70,000	60	$1.5 billion
Shingles (pre-vaccine)	≥ 50 years	1.0 million	46,000	80	$2.4 billion
RSV (pre-vaccine)	≥ 60 years	2.5 million	100,000	8,000	$7.4 billion

1. Adjusted to 2020 dollars
Adapted from NIH and Carrico et al., 2023, *CDC, Bartsch et al., 2020, Harvey et al., 2019, Insinga et al., 2007*

Burden in older adults

Adults older than 65 are another high-risk group for norovirus infections. In the United States, older adults are estimated to account for 17% of illnesses due to norovirus yet comprise 52% of hospitalizations and 94% of deaths. Symptoms are often more severe in this age group and include diarrhea lasting up to nine days and headache, thirst, and vertigo lasting up to 19 days. Older adults are also more likely to be found in certain settings vulnerable to norovirus outbreaks. Long-term care facilities (LTCFs) are the most commonly reported location for norovirus outbreaks, with an estimated 8 – 17% of LTCFs experiencing an outbreak each year. Hospitals are another common setting for norovirus outbreaks. After admittance to a hospital, older adults are more likely to acquire a norovirus infection than younger hospitalized patients. In the United States, norovirus is estimated to result in 3.7 million illnesses, 380,000 outpatient visits, 50,000 hospitalizations, and 1,250 deaths annually for adults over 65. Globally, norovirus is estimated to result in 81 million illnesses and 78,000 deaths annually for adults older than 55.

Burden in other high-risk groups

In addition to young children and older adults, there are other groups that are at high risk for norovirus infection. These include healthcare workers, immunocompromised individuals, military personnel, food handlers, and travelers, including cruise ship passengers. More than 100 outbreaks of norovirus have been described in military units since 1988, reducing operational effectiveness and staff availability for duties. Food handlers are another source of concern. Given the small amount of virus needed for infection, a single individual can be responsible for widespread virus transmission. For example, a norovirus outbreak in 2006 resulting in at least 350 gastroenteritis cases was linked to a single food handler. Another series of high-profile outbreaks occurred at Chipotle restaurants between 2015 and 2018, where 1,100 patrons fell ill after eating at various locations of the chain restaurant. This outbreak resulted in the largest fine in food safety in U.S. history. Travelers are another high-risk group, with more than 20% of travelers with diarrheal symptoms testing positive for norovirus. Cruise ships present a high risk of norovirus outbreaks due to their ideal conditions for transmission: common sources for food and drinks, a semi-closed environment, and older adult passengers that may be more vulnerable to infections and complications arising from gastroenteritis. Outbreaks on cruise ships can be quite severe with infection rates for passengers ranging from 19% to 74%. The CDC reported 84 outbreaks of norovirus on cruise ships between 2010 and 2019.

Our solution: HIL-214

HIL-214 is a bivalent vaccine candidate in development for the prevention of moderate-to-severe AGE caused by norovirus infection. HIL-214 consists of VLPs which are designed to mimic the structure of norovirus and are co-formulated with an alum adjuvant to enhance immunogenicity and stability of the VLPs in solution. HIL-214 is administered intramuscularly via prefilled syringes and has demonstrated stability at standard refrigeration temperatures of 4°C for 24 months.

VLP technology

VLPs are self-assembling structures that mimic the unique and repetitive geometric features that characterize the surface of a live virus. VLPs can be produced using a common range of expression systems, including bacterial, mammalian, or

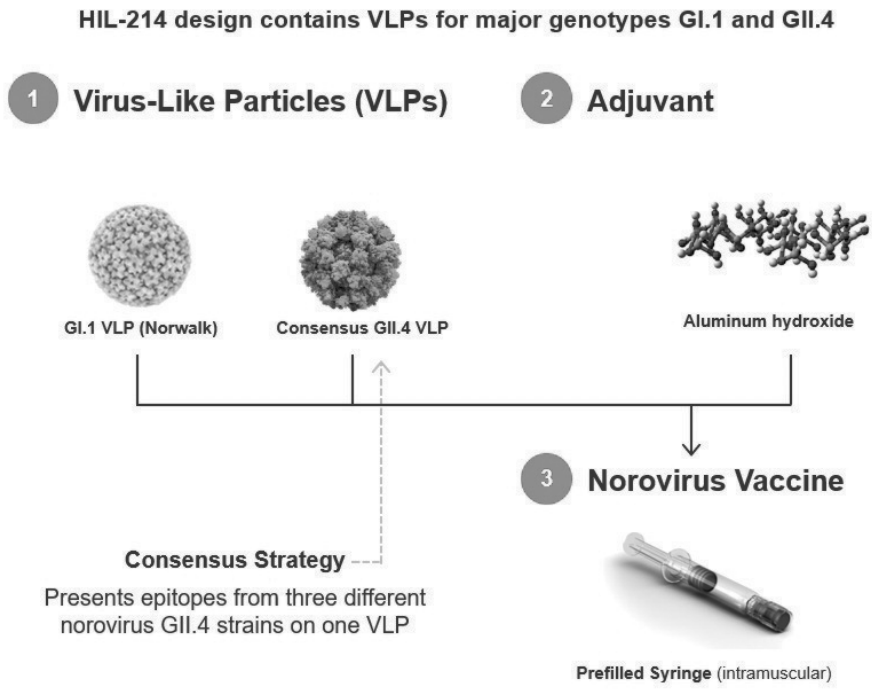
insect cells, and can present a conformationally correct representation of the virus capsid to the immune system. As a result, VLPs can be readily manufactured in cell culture at large scale and offer a highly immunogenic vaccine template. Importantly, VLPs lack a viral genome and can therefore neither replicate nor cause infection, which may provide an important safety advantage over live vaccines.

There is ample precedent for the development of safe and effective vaccines that leverage VLP technology. Gardasil, a commercially available vaccine for human papillomavirus (HPV) developed by Merck, consists of recombinant VLPs self-assembled from the capsid protein of HPV types 6, 11, 16, and 18. A subsequent iteration of the product, known as Gardasil9, added five additional VLPs to its formulation to cover HPV types 31, 33, 45, 52, and 58. Other commercially available VLP vaccines include Cervarix, an HPV vaccine manufactured by GlaxoSmithKline, and Sci-B-Vac, an HBV vaccine developed by VBI Vaccines. There are also a number of VLP vaccines in clinical development for H1N1, HIV, malaria, respiratory syncytial virus, human metapneumovirus, and COVID-19, among other indications. Vaccines that employ VLP technology have been given to millions of patients worldwide.

HIL-214 construct

HIL-214 includes VLPs representing the two genogroups of norovirus responsible for the majority of human infection: GI and GII. Our G1.1 Norwalk VLP was selected based on its potential to promote a broad immune response to GI norovirus strains. In an independent study, infection of human volunteers with GI.1 Norwalk virus resulted in a broad antibody response against GI.1, GI.2, GI.3, and GI.4 strains. Our GII.4 VLP is a consensus sequence of three GII.4 strains that were responsible for major outbreaks in 2002 and 2006: GII.4 Houston/2002, GII.4 Yerseke/2006a, and GII.4 Den Haag/2006b. The GII.4 genotype accounts for two-thirds of norovirus outbreaks worldwide and its prevalence is attributed to its ability to rapidly evolve, with novel variants emerging every two to four years that may evade immunity in the human population. We believe that presenting epitopes from three GII.4 strains on our GII.4 VLP will result in a broader response to GII.4 strains than a VLP presenting a single strain. Sera from adult subjects vaccinated with HIL-214 have been shown to generate antibody titers against a broad range of GI and GII norovirus genogroups. Specifically, HIL-214 resulted in a greater than fourfold rise in antibodies against multiple GI strains (GI.1, GI.5, GI.6) and GII.4 strains (2002, 2006a, 2006b, 2009, 2012). The observation that HIL-214 induced antibodies against GII.4 strains that have emerged after the formulation of our vaccine candidate (GII.4 New Orleans 2009 and GII.4 Sydney 2012) suggests that our GII.4 VLP may protect against newly emerging strains in the future.

HIL-214 also includes aluminum hydroxide (Alhydrogel 2% or alum) as an adjuvant. Alum is the predominant adjuvant used in human vaccines and is a common component of several pediatric vaccines, including those for pneumococcus, diphtheria-tetanus-pertussis (DTaP), Hepatitis A, Hepatitis B and HPV.



HIL-214 clinical data

Overview

HIL-214 has been the subject of nine Phase 1 and Phase 2 clinical trials prior to the initiation of the NEST-IN1 trial, including more than 4,500 subjects of which more than 2,200 subjects have been evaluated for immunogenicity. These subjects have ranged from 6 weeks to 102 years old. An overview of the clinical trials conducted to date by Takeda and its predecessor, LigoCyte Pharmaceuticals, Inc., is tabulated below:

Completed HIL-214 Clinical Trials

Sponsor	Trial no.	Phase	Safety	Immuno	Dose/ regimen	Efficacy	Trial pop.	HIL-214 safety (n)	HIL-214 immuno (n)
LigoCyte	LV01-103	1/2	☑	☑		☑ Challenge	18 – 50 yrs	N/A[1]	N/A[1]
	LV03-104	1	☑	☑	☑		18 – 85 yrs	66	66
	LV03-105	1/2	☑	☑		☑ Challenge	18 – 50 yrs	67	67
Takeda	NOR-210	2	*Generation of serum controls for assay validation*				18 – 49 yrs	50	50
	NOR-107	2	☑	☑			18 – 64 yrs	418	418
	NOR-201	2	☑	☑			18 – 49 yrs	425	425
	NOR-204	2	☑	☑	☑		18 – >85 yrs	311	311
	NOR-211	2b	☑	☑		☑ Field study	18 – 49 yrs	2,355	97
	NOR-202	2	☑	☑	☑		6 wks – 9 yrs	839	839
							TOTAL:	**4,531**	**2,273**

1. *Intranasal formulation of vaccine, not included in HIL-214 safety and immunogenicity subject numbers*

Dose finding and formulation trials in infants and children

A Phase 2 dose finding and formulation trial has been conducted in infants and children for HIL-214. Based on the results from this trial, in addition to considerations around disease burden and maternal antibody concentrations, we have selected the following dose and schedule to continue to evaluate HIL-214 in infants: two doses of 50/150 µg GI.1/GII.4

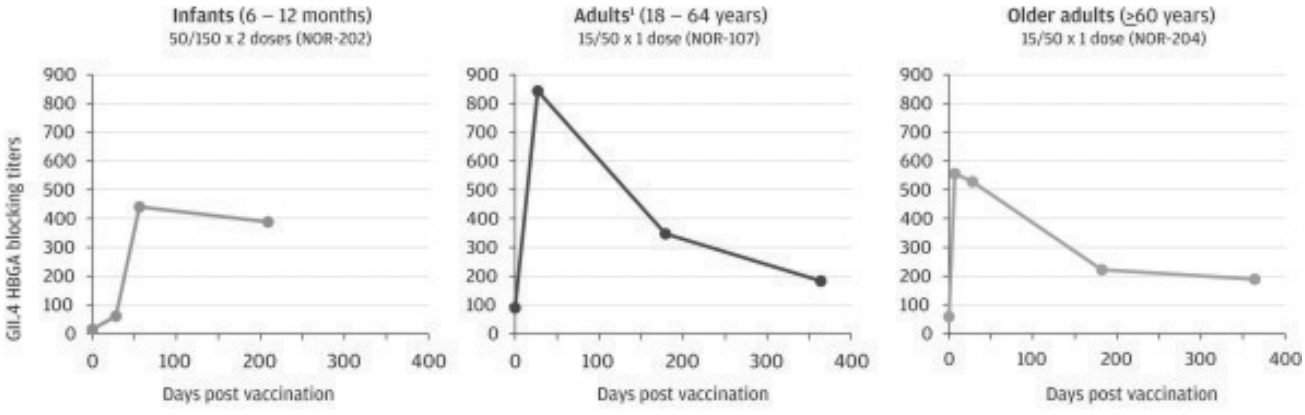
with 500 µg alum given at approximately 5 months of age at the time of the first dose. Further details on this trial are summarized below.

NOR-202—A Phase 2 safety, immunogenicity, and dose finding trial of HIL-214 in infants and children between the ages of 6 weeks and 9 years old. The trial enrolled 840 subjects in Colombia, Panama, and Finland into two cohorts. The first cohort was aged 6 months to 9 years old and received one or two doses of one of four potential HIL-214 formulations containing either 15/15, 15/50, 50/50, or 50/150 µg of the GI.1/GII.4 VLP combination and 500 µg of alum at least 28 days apart. The second cohort was aged 6 weeks to 6 months old and received two or three doses of one of the four potential HIL-214 formulations. All dosages of HIL-214 were generally well tolerated with no AEs related to HIL-214 leading to study withdrawal. All HIL-214 formulations were found to be immunogenic in each pediatric age group as measured by HBGA blocking titers. In children between 6 weeks and 6 months of age, both the two- and three-dose regimens of the 50/150 µg formulation of HIL-214 were found to be immunogenic. In children between 6 and 12 months of age, two doses of the 50/150 µg formulation of HIL-214 were found to be more immunogenic than one dose.

Formulation of HIL-214 across different age groups

	Infants (5 months)	Toddlers (1 – 5 years)	Kids (5 – 17 years)	Adults (18 – 64 years)	Older adults (>65 years)
Dose	50 / 150 µg (GI.1 and GII.4 VLPs)		15 / 50 µg (GI.1 and GII.4 VLPs)		
No. of doses	2 doses		1 dose		
Aluminum	500 µg of aluminum hydroxide				

HIL-214 induced HBGA blocking titers above baseline for all age groups



1. Day 0 titers were collected 28 days prior to vaccination for adult study (NOR-107)

Dose finding and formulation trials in adults

Four dose finding and formulation trials have been conducted in adults for HIL-214. Based on the results of these trials, we selected a single dose of 15/50 µg GI.1/GII.4 VLP combination with 500 µg alum to continue to evaluate HIL-214 in adults. Further details on these trials are summarized below.

LV03-104—A Phase 1, randomized, double-blind, placebo-controlled age- and dose-escalation trial to evaluate the safety and immunogenicity of HIL-214 or saline placebo in 102 adults aged 18 to 85 years old. Forty-eight subjects aged 18 to 49 years old received either two doses of HIL-214 containing GI.1 and GII.4 VLPs (5, 15, 50, or 150 µg of each VLP) or two doses of placebo administered 4 weeks apart. Subsequently, 54 adults aged 18 to 85 years old received two doses of HIL-214 containing 50 µg of each VLP. At all tested dose levels, the vaccine was generally well tolerated and immunogenic as measured by pan-IG, class-specific IgG, and HBGA blocking titers. One dose of vaccine containing 50 µg of each VLP increased GI.1 antibody levels by 118-fold and GII.4 antibody levels by 49-fold in subjects aged 18 to 49 years old. Local reactions were mainly tenderness (71%) and injection site pain (68%) in the 66 subjects who received HIL-214, with no reported fever or vaccine-related serious AEs. A second dose at day 28 provided no apparent improvement in immunogenicity across any of the age groups. The sample size was chosen to obtain indications of safety, reactogenicity, and immune response data but was not powered for statistical significance.

NOR-107—A Phase 2, randomized, double-blind trial to evaluate the safety, immunogenicity, dose, and adjuvant justification of HIL-214 in 420 healthy adults aged 18 to 64 years old. One or two doses of HIL-214 were administered 28

days apart in a factorial design testing combination of 15, 50 or 150 µg of each VLP with 0, 15 or 50 µg of monophosphoryl lipid A (MPL) and 167 or 500 µg of alum. For subjects receiving a single dose of HIL-214, a hepatitis A vaccine (Havrix) was given as a control to maintain the blinding. The trial demonstrated that the adjuvant MPL did not significantly improve immunogenicity, and that seroresponse rates (the percentage of subjects with a greater than four-fold rise in antibody levels) were greater with 500 µg of alum than with 167 µg of alum. The most common AEs were injection site pain (46%), headache (18%), and fatigue (14%) in the 420 subjects studied, with no vaccine-related serious AEs reported. The study also showed that a second dose of the 15/50 µg GI.1/GII.4 formulation provided no apparent improvement in immunogenicity. This study was powered for statistical significance.

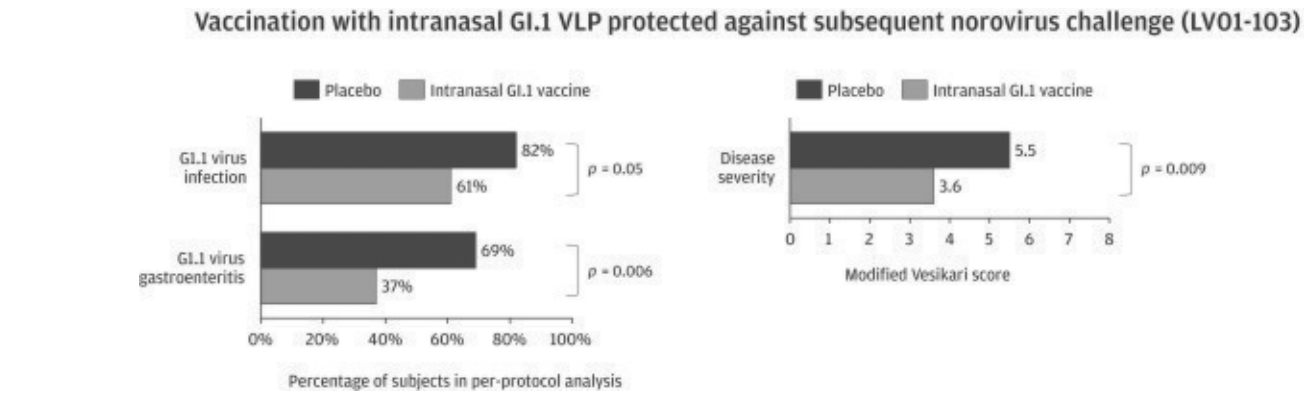
NOR-201—A Phase 2, randomized, double-blind trial to evaluate the safety and immunogenicity of HIL-214 in 454 adults aged 18 to 49 years old. Enrolled subjects were randomly assigned among three groups receiving one dose of saline placebo or HIL-214 containing either 15/50 or 50/50 µg GI.1/GII.4 VLP combinations adjuvanted with 50 µg of MPL and 500 µg of alum. Both HIL-214 formulations were well tolerated and immunogenic, although GII.4 responses were higher with the 15/50 VLP combination (although the difference did not reach statistical significance). The most common AEs were pain near the injection site (69%) and muscle pain (22%) in the 299 subjects who received HIL-214, with no vaccine-related serious AEs reported. The results from this trial suggest that the 15/50 µg dose may be the optimal formulation to evaluate in adults. The sample size was chosen to provide a clinical database to support initiation of larger Phase 2 and 3 studies but was not powered for statistical significance.

NOR-204—A Phase 2, randomized, double-blind trial to evaluate the safety, immunogenicity, dose formulation, and dose regimen of HIL-214 in 320 healthy adults aged 18 to over 85 years old. Older adults were stratified into three groups of 60-74 years, 75-84 years and greater than 85 years. A cohort of younger adults of 18 to 49 years was enrolled for comparison. One or two doses of HIL-214 were administered in a 15/50 µg GI.1/GII.4 VLP combination adjuvanted with 500 µg alum with or without 50 µg of MPL. For subjects receiving a single dose of HIL-214, a saline placebo was given as a control to maintain the blinding. The most common AEs were injection site pain (33%) and fatigue (12%) in the 73 subjects studied, with no vaccine-related serious AEs reported. The results of this trial suggest that there was no statistically significant benefit of either MPL or a second dose on immunogenicity, and further, suggested that the formulation of 15/50 µg GI.1/GII.4 VLP combination and 500 µg alum may be the optimal formulation to evaluate in adults. The trial also found that the antibody response in each of the older age groups was similar to that in the young adult age group. This study was powered for statistical significance.

Efficacy trials in adults

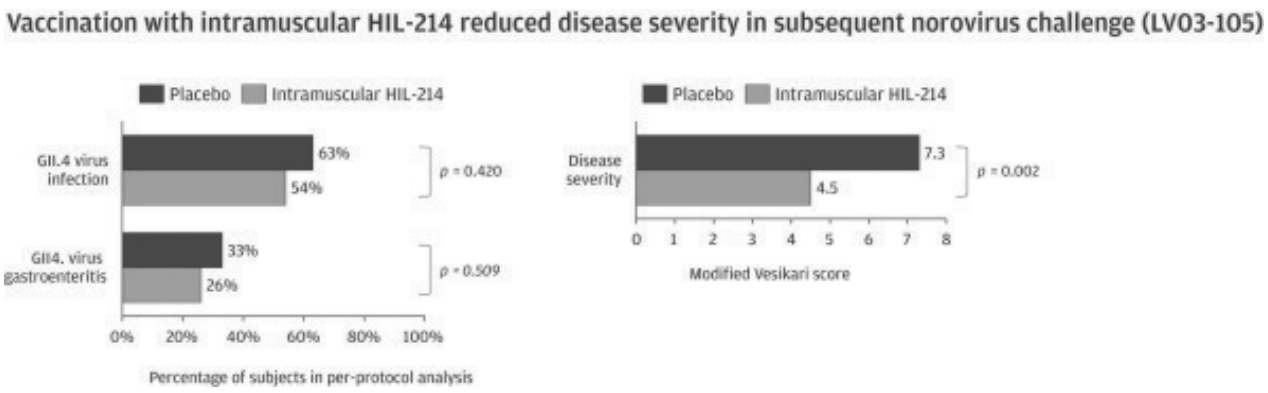
Proof-of-concept of the efficacy of HIL-214 in adults has been demonstrated across three clinical trials: two Phase 1/2 challenge trials and a Phase 2b field efficacy trial. Further details on these trials are summarized below.

Challenge trial (LV01-103)—A Phase 1/2, randomized, double-blind, placebo-controlled trial to evaluate the efficacy of an intranasal GI.1 VLP vaccine candidate after challenge with a live, vaccine-matched GI.1 norovirus strain in 98 healthy adults aged 18 and 50 years old. The vaccine formulation used in the trial contained 100 µg of GI.1 VLP and was adjuvanted with chitosan and MPL. Subjects were randomized to receive either two doses of saline placebo or GI.1 vaccine delivered intranasally three weeks apart. Subjects were then challenged with a live GI.1 virus to test the effect of vaccination on norovirus infection and disease. Vaccination significantly reduced the frequency of GI.1 infection (occurring in 61% in vaccine recipients vs. 82% in placebo recipients, $p = 0.05$). Vaccination also significantly reduced the frequency of GI.1 virus gastroenteritis (occurring in 37% of vaccine recipients vs. 69% of placebo recipients, $p = 0.006$). Furthermore, disease severity was significantly reduced as measured by modified Vesikari score, which is a validated common metric for rating the severity of gastroenteritis symptoms based on a scale of 20 (3.6 for vaccine recipients vs. 5.5 for placebo recipients, $p = 0.009$).



A p-value is the probability that the reported result was achieved purely by chance, such that a p-value of less than or equal to 0.05 means that there is a less than or equal to 5% probability that the difference between the control group and the treatment group is purely due to chance. A p-value of 0.05 or less typically represents a statistically significant result. The United States Food and Drug Administration's (FDA's) evidentiary standard when evaluating the results of a clinical trial generally relies on a p-value of less than or equal to 0.05.

Challenge trial (LV03-105)—A Phase 1/2, randomized, double-blind, placebo-controlled trial to evaluate the efficacy of HIL-214 after challenge with a live, GII.4 norovirus strain. The HIL-214 formulation used in the trial contained a 50/50 µg ratio of GI.1 and GII.4 VLPs and was adjuvanted with 500 µg of alum and 50 µg MPL. Subjects were between 18 and 50 years of age and received two doses of either saline placebo or GI.1/GII.4 vaccine intramuscularly four weeks apart. Subjects were then challenged with a live GII.4 virus to test the effect of vaccination on norovirus infection or disease. HIL-214 led to a significant reduction in the severity of vomiting or diarrhea by subject assessment (20% in vaccine recipients vs. 42% in placebo recipients, p = 0.028). HIL-214 also led to a significant reduction in disease severity as measured by modified Vesikari score (4.5 in vaccine recipients vs. 7.3 in placebo recipients, p = 0.002). The results of this trial showed a directional, albeit not statistically significant, reduction in frequency of AGE (26% vs. 33%) and infection (54% vs. 63%) for the HIL-214 group relative to the placebo group after challenge. We believe the lack of statistical significance was potentially due to a lower than expected infection and illness rate; only 57 of the 98 subjects were successfully infected with norovirus which lowered the statistical power for the study.



Field efficacy trial (NOR-211)—A Phase 2b, randomized, double-blind, placebo-controlled trial to evaluate the efficacy of HIL-214 to prevent norovirus infection and moderate-to-severe AGE in the field setting. The trial was conducted in U.S. military recruits at a single base in Great Lakes, Illinois over the course of two winter seasons (2016 – 2018). In total, 4,712 subjects aged 18-49 years old were enrolled in the trial and received one dose of either saline placebo or HIL-214 (15/50 µg of GI.1/GII.4 with 500 µg of alum as an adjuvant). The primary endpoint of the NOR-211 trial was the efficacy of a single dose of HIL-214 compared to placebo to prevent cases of moderate to severe AGE due to infection by genotype matched norovirus strains represented in the vaccine (i.e., GI.1 or GII.4). The low attack rate of norovirus strains represented in the vaccine resulted in insufficient cases to assess the primary endpoint. Thirty vaccine-matched AGE cases were required to provide 80% statistical power to detect 70% vaccine efficacy; however, only 6 vaccine-matched cases occurred during the trial. Of those 6 cases, 5 were in the placebo group, corresponding to 80% vaccine efficacy for genotype matched cases of AGE (p=0.1417). On account of this lower than anticipated attack rate of GI.1 and GII.4, the statistical analysis plan was amended prior to locking the database and unblinding the trial. While only 6 vaccine-matched

AGE cases caused by GII.4 were observed, a total of 36 AGE cases caused by any norovirus genotype was observed, which was a sufficient number to evaluate the secondary endpoint of HIL-214 against moderate-to-severe AGE due to norovirus infection irrespective of genotype. Of those 36 cases, 26 were in the placebo group, corresponding to 62% vaccine efficacy (p = 0.0097) for any norovirus genotype, including those not included in HIL-214. In sum, this trial provided statistically significant evidence of heterotypic protection against at least one non-vaccine norovirus strain (GII.2). This trial also provided encouraging evidence of protection against vaccine-matched strains.

Vaccination with HIL-214 reduced the incidence and severity of norovirus-related illness (NOR-211)

	Cases of moderate-to-severe AGE			Viral efficacy	
	Pathogen	Placebo N = 2,357	HIL-214 N = 2,355	%	*p* value
1°	HIL-214 vaccine strain only[1]	5	1	80.0	*p* = 0.142
2°	Any norovirus strain	26	10	61.8	*p* = 0.0097
Post-hoc	GII.2 strain	21	9	57.4	*p* = 0.0321

AGE severity		
	Placebo N = 2,357	HIL-214 N = 2,355
Moderate	10	4
Severe	17	8

1. GI.1 or GII.4.
Note that case numbers in left and right tables may differ due to case definition

One potential explanation for the cross-protection observed in this trial is that HIL-214 may have induced cross-reactive antibodies against GII.2 viruses (evidence of heterotypic protection). In support of this hypothesis, HIL-214 was found to induce both binding and HBGA-blocking antibodies against GII.2 VLPs.

Safety results in infants and children

Safety data for HIL-214 in infants and children were collected for over 800 subjects in NOR-202, a Phase 2 safety, immunogenicity and dose finding trial. This trial demonstrated that all doses of HIL-214 were well tolerated, and there were no HIL-214-related AEs leading to trial withdrawal. AEs were largely mild to moderate in intensity and tended to subside in 3 to 4 days. In children between 6 weeks to 6 months of age who received two doses of HIL-214, the most common reactions were irritability / fussiness (19—28%), drowsiness (16—21%), pain near the injection site (9—21%), and diarrhea (10—19%) in the 180 subjects studied. In children between 6 months and 9 years of age who received two doses of HIL-214, the most common reactions were pain near the injection site (21—33%), fatigue (16—24%), headache (14—21%), and irritability / fussiness (10—20%) in the 238 subjects studied. A comparison of the reactogenicity of HIL-214 to other common pediatric vaccinations is tabulated below. These data are presented for informational purposes only, as the comparison in the table below is not based on head-to-head clinical studies and these data may not be comparable due to differences in trial designs and populations studied.

Pediatric safety summary for HIL-214

Disease	Vaccine	Age	Local reactions	Systemic reactions	
			Pain, swelling or redness	Fever > 38°C	Irritability or fussiness
Norovirus	HIL-214	6 weeks – 6 months[5]	9 – 21%[1]	2 – 9%[1]	19 - 28%[1]
		6 months – 9 years[5]	21 – 33%[1]	7 – 8%[1]	10 - 20%[1]
Pneumococcal	Prevnar 13	2 – 15 months	20 – 42%[3,4]	24 – 37%[3]	80 - 86%[3]
Rotavirus	Rotarix	6 – 24 weeks	Oral – N/A	25 – 28%[1]	42 - 52%[1]
	RotaTeq	5 – 36 weeks		17 – 20%[2]	4 - 7%[2]
Pertussis	Daptacel (TDaP)	2 – 6 months	1 – 6%[2,4]	8 – 24%[2]	32 - 40%[2]
	Whole cell DTP	2 – 6 months	5 – 11%[2,4]	65 – 74%[2]	73 - 85%[2]
MMRV	M-M-R II & Varivax	12 – 23 months	10 – 16%[4]	15%	7%
	ProQuad	12 – 23 months	8 – 14%[4]	22%	7%
Polio	OPV	2 months – 6 years	Oral – N/A	< 1%	< 1%

1. After doses one or two. 2. After doses one, two, or three. 3. After doses one, two, three, or four. 4. Refers to redness or swelling only 5. Data from NOR-202.

Safety in adults

Safety data for HIL-214 in adults have been collected for over 4,000 subjects across seven clinical trials. These trials have demonstrated that HIL-214 was well tolerated, and there were no HIL-214-related AEs leading to trial withdrawal. In the NOR-211 field efficacy trial of military recruits, the most common reaction was pain near the injection site with a mean duration of 2 days (48% for HIL-214 vs. 38% for placebo) in a safety subset of 377 subjects. Systemic AEs were found to occur at a similar rate to placebo (56% for HIL-214 vs. 60% for placebo).

In NOR-211 adult study, local AEs all mild/moderate with systemic AEs similar to placebo

	Placebo *n=186*	(%)	HIL-214 *n=191*	(%)
Local AEs				
Any	71	(38.4)	93	(49.2)
Mild	53	(28.6)	64	(38.4)
Moderate	16	(8.5)	28	(14.8)
Severe	1	(0.5)	0	(0)
Systemic AEs				
Any	112	(60.2)	108	(56.6)
Mild	64	(34.4)	60	(31.4)
Moderate	42	(22.6)	40	(21.5)
Severe	5	(2.7)	6	(3.1)

Safety data for HIL-214 in older adults (>60 years old) have also been collected for 294 subjects in NOR-204, a Phase 2 safety, immunogenicity, and dose finding trial. This study found that local AEs were mostly mild in intensity and injection-site pain was the most frequently reported symptom. In addition to these completed trials, a Phase 2 trial is currently ongoing to evaluate the long-term safety and immunogenicity of HIL-214 in 528 subjects between 18 and 85 years of age up to 5 years post vaccination (NOR-213). Interim data from this study have shown no vaccine-related serious AEs reported and maintenance of antibody levels above baseline at 3 years post vaccination. A comparison of the reactogenicity of HIL-214 to other common adult vaccinations is tabulated below. These data are presented for informational purposes only, as the comparison in the table below is not based on head-to-head clinical studies and these data may not be comparable due to differences in trial designs and populations studied.

Adult safety summary for HIL-214

Disease	Vaccine	Age	Local reactions	Systemic reactions	
			Pain at injection site	Fever > 38°C	Headache
Norovirus	HIL-214	18 to 49 years[4]	48%	6%	35%
		>60 years[5]	33%	<1%	8%
COVID-19	Comirnaty	16 to 55 years	78 - 84%[1]	4 - 16%[1]	44 - 54%[1]
	Moderna	18 to 64 years	87 - 90%[1]	1 - 17%[1]	35 - 63%[1]
HPV	Gardasil 9	16 to 26 years	71 - 74%[2]	2 - 3%[2]	15%
Influenza	Afluria	18 to 64 years	48%	1%	22%
	FluBlok	>50 years	19%	<1%	13%
Shingles	Shingrix	>50 years	69 - 88%[3]	14 - 28%[3]	29 - 51%[3]

1. After doses one or two. 2. After doses one, two, or three. 3. Range given for patients 50 - 59, 60 - 69, and >70 years of age 4. Data from NOR-211. 5. Data from NOR-204.

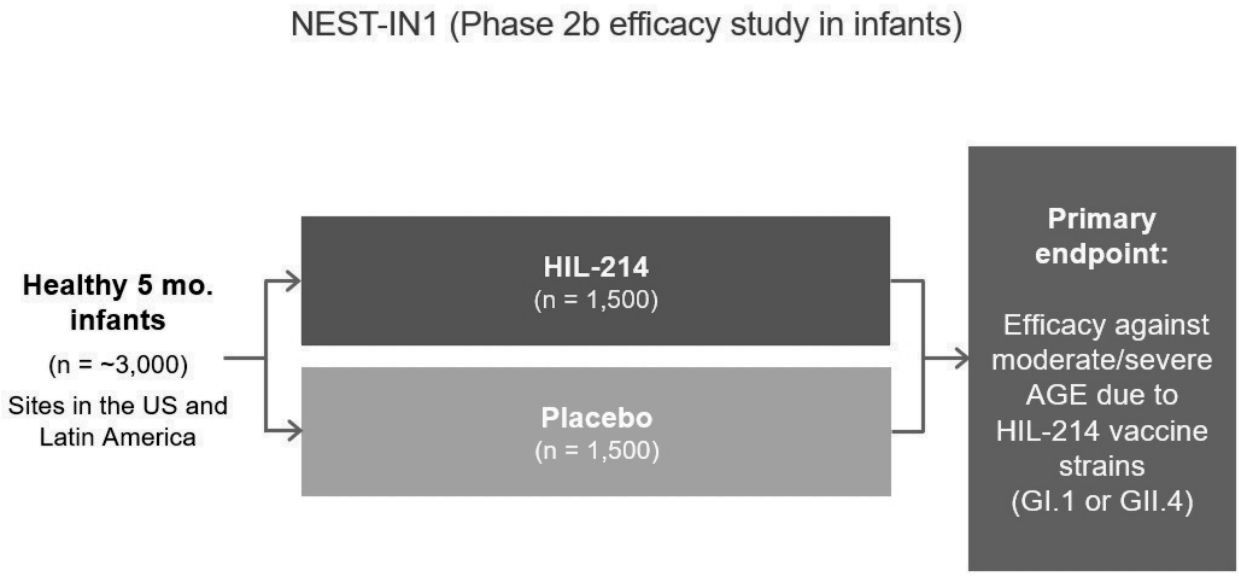
Our clinical program in infants

Phase 2b – infant efficacy trial (NEST-IN1)

We plan to build on the extensive clinical data generated to date through conduct of our ongoing clinical trial in infants. We believe that initial development of HIL-214 in infants will de-risk its development given the endemic nature of disease in this population, which allows for rapid case accrual and enrollment of subjects without pre-existing immunity to norovirus.

In May 2022, we initiated our ongoing NEST-IN1 Phase 2b clinical trial to evaluate the efficacy, safety and immunogenicity of HIL-214 in approximately 3,000 infants. This clinical trial is a randomized, double-blind, placebo-controlled trial in infants of approximately 5 months of age at time of initial vaccination at sites in the United States and Latin America. We believe approximately 5 months of age is the optimum time to begin immunization as it is prior to the sharp increase in incidence of norovirus that begins at 6 months of age and coincides with the waning of maternal antibodies to norovirus. Subjects are randomized 1:1 to receive either HIL-214 or placebo. In the vaccine arm, subjects received HIL-214 (50/150 µg GI.1/GII.4 VLP combination with 500 µg alum) in a two-dose regimen delivered 28 to 56 days apart. In the control arm, subjects received saline placebo at the corresponding timepoints. The dosage and scheduling were based on learnings from the NOR-202 Phase 2 trial. The primary objective of NEST-IN1 is to evaluate the protective efficacy of HIL-214 against moderate or severe AGE events associated with GI.1 or GII.4 norovirus strains (excluding certain co-infections) during a pre-determined surveillance period that begins one month after the administration of the second dose of HIL-214. A key secondary endpoint is the evaluation of the protective efficacy of HIL-214 against any GI or GII norovirus strain. Other secondary endpoints include the evaluation of safety and immunogenicity of HIL-214.

In May 2022, we completed enrollment of the prespecified 200 subject run-in for NEST-IN1. We resumed enrollment in NEST-IN1 in August 2022, following the prespecified safety assessment by the clinical trial's data monitoring committee. In December 2022, we reported positive interim immunogenicity results for the first 200 subjects of NEST-IN1. We completed enrollment for NEST-IN1 in April 2023. We expect to report top-line safety and clinical efficacy data in mid-2024.



We have developed and are qualifying a number of clinical assays to support the determination of our primary and secondary endpoints. These include an assay to detect norovirus in stool samples and determine norovirus genogroup (e.g., GI or GII), a sequencing assay to determine norovirus genotype (e.g., GI.1 or GII.4), and a co-pathogen assay to detect other pathogens that may cause AGE (e.g., rotavirus or Salmonella). The immunogenicity of HIL-214 will be evaluated using assays that measure HBGA-blocking antibody titers and pan-Ig antibody titers. We have designed the assays for NEST-IN1 based on learnings from the NOR-211 Phase 2b study and the NOR-202 Phase 2 study in adults, as well as preliminary feedback Takeda received from the FDA and European Medicines Agency (EMA). We reported interim safety data for the first 200 subjects in the third quarter of 2022 following a positive recommendation from the data monitoring committee to continue enrollment. We reported positive interim immunogenicity data for the first approximately 200 subjects in the fourth quarter of 2022 where we observed immune responses generally consistent with prior studies of HIL-214 in infants. Geometric Mean Titers (GMTs) of pan-IG antibodies 28 days following the second dose were 11,102.0 IU/mL and 2,185.5 IU/mL for GI.1 and GII.4, respectively, for HIL-214 compared to 59.6 IU/mL and 73.5 IU/mL for GI.1 and GII.4, respectively, for placebo. These titers corresponded to a Geometric Mean Fold Rise (GMFR) versus baseline of more than 18-fold for HIL-214. Seroresponse rates (SRRs) for HIL-214, defined in NEST-IN1 as the percentage of subjects with at least a 4-fold increase in pan-Ig (immunoglobulin) antibody titers 28 days following the second dose compared to pre-vaccination baseline, were 99.0% for GI.1 and 86.9% for GII.4. SRRs for placebo were 4.1% and 3.1% for GI.1 and GII.4, respectively.

Phase 3 infant efficacy trial

Based on the results from NEST-IN1, if positive, we intend to consult with key regulatory authorities and initiate a Phase 3, randomized, double-blind, placebo-controlled trial to evaluate the efficacy, safety, and immunogenicity of HIL-214 in a larger clinical trial. We expect that this trial will enroll approximately 7,000 to 12,000 subjects that will be randomized 1:1 into the vaccine or control arm. Trial sites under consideration are located in the United States, Latin America, Europe, and Japan.

Other trials in infants

We are planning additional trials in infants to support regulatory submissions. These include a Phase 1, randomized, double-blind, placebo-controlled trial to establish whether the safety and immunogenicity data obtained is consistent with that previously obtained for non-Japanese pediatric subjects, and to support the potential inclusion of Japanese infants in a Phase 3 trial of HIL-214. These include a Phase 2 trial to evaluate the immune response to routine pediatric

vaccinations when co-administered with HIL-214, which is designed to inform our global strategy for our pivotal Phase 3 infant efficacy trial with HIL214.

We also expect to conduct a Phase 3 trial to evaluate lot-to-lot consistency of HIL-214.

We believe that successful completion of this clinical program in infants, together with existing clinical data, will support regulatory submissions for marketing approval in most territories of the world, including the United States, Europe, Japan, and Latin America.

Our immunobridging strategy to other age groups

Overview

If we are successful in obtaining approval for HIL-214 in infants, we plan to subsequently seek approval of HIL-214 in additional age groups, including older children and adolescents (2 to 17 years of age), adults (18 to 59 years of age), and older adults (60 years of age and older). Our preferred strategic approach for seeking approval in these populations is through conducting immunobridging trials, which aim to demonstrate non-inferiority of immune response between a reference age group (i.e., infants) and target age groups. These trials require an appropriate serological surrogate for efficacy and can potentially support regulatory submissions seeking approval to expand to these other age groups without the need for an efficacy trial. Key requirements for an immunobridging strategy include:

- **Comparability.** The same or comparable immune assay should be used in the reference and target populations.
- **Predictability.** The immune assay should be reasonably likely to predict protection from infection or disease. Regulatory authorities are more likely to accept functional immune assays (e.g., blocking or neutralization assays) than non-functional immune assays (e.g., assays that measure bulk antibody levels).
- **Well-defined non-inferiority margins.** Non-inferiority margins should be prospectively defined and justified to regulatory authorities.

We believe the most likely serological surrogate will be blocking antibodies to HBGAs, which have previously been shown to correlate with protection against norovirus. We are planning to collect HBGA-blocking titers for all subjects in our planned Phase 2b and Phase 3 infant efficacy trials to use as a reference for immunobridging to other age groups. In addition to HBGA-blocking antibodies, we are also exploring the measurement of other immune parameters that may be reasonably likely to predict protection.

If we are not able to confirm an appropriate serological surrogate in our planned infant efficacy trials, or if the FDA or EMA do not agree with our proposed immunobridging strategy, we plan to directly evaluate HIL-214 for efficacy in older adults (65 years of age and older). We would plan to conduct this trial across multiple sites at high-risk for norovirus outbreaks, including nursing homes, assisted living facilities, and other older adult communities.

Historical precedent for immunobridging

A number of vaccines have successfully used immunobridging to expand the approval of a vaccine to those in other age groups, without conducting further efficacy studies, including Boostrix, Gardasil, Cervarix, and Vaxchora. For example, Boostrix used a prior infant efficacy study to bridge to older subjects and included the use of a different vaccine strength and regimen in infants and older age groups. This immunobridging strategy was based on demonstrating non-inferiority of pertussis antigen seroresponses in adolescents (10 to 18 years of age), adults (19 to 64 years of age), and older adults (65 years of age and older) to prior infant responses in efficacy trials. Of particular note, this strategy was successful for Boostrix even in the absence of an established correlate of protection for pertussis.

HIL-214 commercial opportunity

The global vaccine market is estimated to have been over $140 billion in 2021. Pneumococcal vaccines have historically been the largest vaccine category, with $7 billion in sales in 2021. COVID-19 vaccines were the largest category in 2021 and 2022. We believe that the increased attention given to infectious diseases during the COVID-19 pandemic, and the important role of vaccines in disease prevention, is likely to further increase the size of the global vaccine market.

There are currently no approved vaccines for the prevention of norovirus-related illness. However, there are market analogues that we believe we can use to estimate the size of the commercial opportunity for HIL-214. In the pediatric market, we believe that rotavirus vaccines are the closest analogue to HIL-214. Rotavirus was the leading cause of pediatric viral AGE before the introduction of the rotavirus vaccines, Rotarix and RotaTeq. These vaccines, approved only in infants, are now widely adopted worldwide, with many countries achieving vaccination rates above 80% among one-year-olds. Rotavirus vaccines generated more than $1.5 billion in sales in 2021. For comparison, norovirus today has a

similar morbidity, mortality, and economic burden in children as rotavirus did before the introduction of rotavirus vaccines. When considering all age groups, the overall burden of norovirus is greater than that of rotavirus.

In the older adult market, we believe that Shingrix, a recombinant protein vaccine developed by GSK to prevent shingles, and the newly launched RSV vaccines developed by GSK and Pfizer, are analogues for HIL-214 due to the similarities in morbidity, mortality and economic burden between shingles, RSV and norovirus each before the introduction of a vaccine. Shingrix generated $4.4 billion in sales in 2023. The RSV Arexvy and Abrysvo, developed by GSK and Pfizer, respectively, generated $1.2 billion in sales in the third quarter of 2023. For comparison, norovirus today has a greater morbidity, mortality, and economic burden than shingles did before the introduction of shingles vaccines. Prior to shingles vaccines becoming available, shingles was estimated to result in 1 million illnesses, 46,000 hospitalizations, and 80 deaths each year among adults over 50 years of age in the United States, for a total societal cost of $2.4 billion. In contrast, norovirus results in 22 million illnesses, 96,000 hospitalizations, and 1,350 deaths each year among all age groups in the United States, for a total societal cost of $10 billion. Furthermore, we believe that there is a commercial opportunity for a norovirus vaccine in other groups at high risk for norovirus infection, such as healthcare workers, immunocompromised individuals, military personnel, food handlers, and travelers, including cruise ship passengers.

A key element of our commercial strategy is to receive advisory body recommendations for the use of HIL-214. In particular, we are focused on the ACIP, which is an advisory body of the CDC that develops vaccine recommendations for children and adults in the United States. New pediatric vaccines that received a preferred recommendation from ACIP are nearly universally adopted by pediatricians and are often required by schools. Rotavirus vaccines received an ACIP recommendation in 2006, which has contributed to their broad uptake in the United States. Following completion of our planned Phase 2b and 3 trials in infants, we expect ACIP to review these data with the goal of having ACIP recommend HIL-214 for routine pediatric use. We also plan to pursue an ACIP recommendation in the older adult population.

Other development program

We have in-licensed HIL-216 from Chengdu Kanghua Biological Products Co., Ltd. (Kangh), a Chinese company. Our license provides world-wide rights to the vaccine outside of the Chinese market. HIL-216 includes six common norovirus genotypes, GI.1, GII.2, GII.3, GII.4, GII.6 and GII.17. We plan to develop HIL-216 as a potential next-generation, higher valency, VLP-based norovirus vaccine. The IND for HIL-216 was cleared by the FDA in September 2023. We plan to initiate our first Phase 1 clinical trial with HIL-216 in late 2024.

Competition

Our industry is characterized by rapidly advancing technologies, intense competition, and strong emphasis on proprietary products. According to EvaluatePharma, October, 2021, the current vaccine market is concentrated among a few global biopharmaceutical companies including BioNTech, CSL Bering, GlaxoSmithKline, Merck, Moderna, Pfizer, Sanofi, and Takeda, which together account for the majority of global vaccine sales. Other pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions are also active in the vaccine market given the continuing global need for both existing and new vaccines.

While we believe that our team, technology, strategy, and depth of clinical data relative to other products in clinical development provide us with a strong competitive advantage, if HIL-214 receives marketing approval, we will have to compete with new products and therapies that may become available in the future. The key competitive factors that will affect the success of HIL-214 are similar to those faced by other vaccine products: safety, immunogenicity, protective efficacy, duration of effect, convenience of administration, price, public health policy, and reimbursement by third-party payors.

There are currently no approved vaccines for the prevention of norovirus-related illness. While we are not aware of all of our competitors' efforts, based on public statements, we believe that several companies are in various stages of developing a vaccine for norovirus including China National Biotec, Chongqing Zhifei Biological, Icon Genetics, Moderna and Vaxart. We believe that China National Biotec, Chongqing Zhifei Biological and Icon Genetics are also focused on developing a vaccine consisting of VLPs representing the GI and GII genogroups of norovirus. Further, we believe that China National Biotec and Chongqing Zhifei Biological are also developing a pediatric vaccine for the prevention of norovirus-related illness. We believe that HIL-214 is well positioned to be the first norovirus vaccine approved in any market worldwide.

Manufacturing

We do not have, nor do we plan to establish, large-scale manufacturing facilities that are compliant with current Good Manufacturing Practices (cGMP). For our Phase 2b infant efficacy trial, we are using clinical material that was previously manufactured by Takeda. We have relied on, and plan to continue to rely on, third-party manufacturers to produce cGMP

material, including bulk intermediate VLPs, drug substance and drug product, for our future clinical trials and commercial supply, if approved.

Intellectual property

Intellectual property, including patents, trade secrets, and trademarks, is important to our business. Our commercial success depends in part on our ability to obtain and maintain proprietary intellectual property protection for HIL-214, as well as for future vaccine candidates and novel discoveries, product development technologies, and know-how. Our commercial success also depends in part on our ability to operate without infringing, misappropriating or violating the intellectual property and proprietary rights of others and to prevent others from infringing, misappropriating or violating our intellectual property and proprietary rights. Our policy is to develop and maintain protection of our proprietary position by, among other methods, licensing or filing U.S. and foreign patents and applications relating to our technology, inventions, and improvements that are important to the development and implementation of our business.

Our patent portfolio, comprising patents and patent applications exclusively licensed to us, is built with a goal of establishing broad protection that generally includes, for the vaccine candidate compound, claims directed to composition of matter, pharmaceutical compositions or formulations, methods of synthesis, and methods of use of such pharmaceutical compositions or formulations. As of March 1, 2024, our patent portfolio covering HIL-214 consists solely of patents and patent applications exclusively licensed from Takeda. Subject to the terms of the Takeda License we entered into with Takeda on July 2, 2021, we have licensed from Takeda exclusive commercialization rights worldwide, excluding Japan, to patents and patent applications covering the composition of matter, formulation, use and/or manufacture of HIL-214. Our patent portfolio comprises 11 distinct patent families protecting the technology relating to HIL-214 composition of matter, methods of manufacturing HIL-214, formulations of HIL-214 products, as well as methods of use of HIL-214. As of March 1, 2024, our portfolio consists of approximately 25 issued U.S. patents, 6 pending U.S. patent applications, 1 pending international PCT application, 74 issued foreign patents including 7 issued European patents subsequently validated in individual European countries, and 47 foreign patent applications pending in major international markets. The issued patents and pending applications have nominal expiration dates ranging from 2027 to 2042, without accounting for any available patent term adjustments or extensions.

More specifically, of the 11 distinct patent families, we have in-licensed two patent families relating to manufacturing methods for norovirus VLPs. One of these families contains four U.S. patents projected to expire from 2028 to 2029, as well as a granted patent in each of Canada, Hong Kong, Europe, Republic of Korea and Singapore and two granted patents in Australia, also projected to expire in 2028, in each case without accounting for any available patent term adjustments or extensions. The European patent in this family was validated in Belgium, Bulgaria, Switzerland, Czech Republic, Germany, Denmark, France, the United Kingdom, Hungary, Ireland, Netherlands, Poland and Sweden. There is an additional pending application in Singapore, projected to expire in 2028, without accounting for any available patent term adjustments or extensions.

The other patent family covering manufacturing methods contains two U.S. patents projected to expire from 2033 to 2035, as well as a granted patent in each of Argentina, Australia, Europe, Hong Kong, India, Iran, Jordan, Lebanon, Republic of Korea, Mexico, Taiwan and Uruguay, all projected to expire in 2033, in each case without accounting for any available patent term adjustments or extensions. The European patent in this family was validated in Belgium, Switzerland, Czech Republic, Germany, France, the United Kingdom, Ireland and Netherlands. There are additional pending patent applications in each of Argentina, Bangladesh, Canada, China, Gulf Co-Operation Council, Pakistan, Singapore, Venezuela and the U.S., all projected to expire in 2033, in each case without accounting for any available patent term adjustments or extensions.

We have also in-licensed six patent families covering VLP compositions for HIL-214 and methods of use of HIL-214. One of these families contains seven U.S. patents, all projected to expire in 2027, as well as two granted patents in Europe, two granted patents in Hong Kong and a granted patent in each of Australia, Canada, Republic of Korea, Singapore, also projected to expire in 2027, in each case without accounting for any available patent term adjustments or extensions. One European patent in this family was validated in Austria, Belgium, Switzerland, Germany, Denmark, Spain, Finland, France, the United Kingdom, Greece, Ireland, Italy, Lithuania, Netherlands, Sweden and Turkey. A second European patent in this family was validated in Belgium, Bulgaria, Switzerland, Czech Republic, Germany, Denmark, Spain, Finland, France, the United Kingdom, Hungary, Ireland, Italy, Netherlands, Poland and Sweden. There is an additional pending application in Singapore, projected to expire in 2027, without accounting for any available patent term adjustments or extensions.

A second family covering VLP compositions and methods of use contains five U.S. patents projected to expire from 2027 to 2028, as well as two granted patents in each of Australia and China and a granted patent in each of Canada, Macau and Hong Kong, projected to expire from 2027 to 2028, in each case without accounting for any available patent term

adjustments or extensions. There is an additional pending application in the U.S. and two in Singapore, projected to expire in 2028, in each case without accounting for any available patent term adjustments or extensions.

A third family covering VLP compositions and methods of use contains two U.S. patents projected to expire in 2029, as well as two granted patents in Republic of Korea and a granted patent in each of Australia, Canada, China, Macau, Europe, Hong Kong and Singapore, projected to expire in 2029, in each case without accounting for any available patent term adjustments or extensions. The European patent in this family was validated in Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Netherlands, Norway, Poland, Spain, Sweden, Switzerland, Turkey and the United Kingdom. There is an additional pending application in each of China, Europe and Hong Kong, all projected to expire in 2029, in each case without accounting for any available patent term adjustments or extensions.

A fourth family covering VLP compositions and methods of use contains four US patents projected to expire in 2032, 1 pending United States patent application, as well as three granted patents in Eurasia, two granted patents in Australia, Europe, Mexico, New Zealand, Philippines and South Africa and a granted patent in each of Algeria, Canada, Chile, the Dominican Republic, Georgia, Hong Kong, Israel, India, Republic of Korea, Morocco, Malaysia, Peru, Singapore, Tunisia, Ukraine and Vietnam, also projected to expire in 2032, in each case without accounting for any available patent term adjustments or extensions. The first European patent in this family was validated in Austria, Belgium, Switzerland, Germany, Spain, France, the United Kingdom, Italy, Netherlands, Poland and Sweden. The second European patent in this family was validated in Austria, Belgium, Czech Republic, Germany, Denmark, Spain, Finland, France, the United Kingdom, Ireland, Italy, Netherlands, Norway, Poland, Sweden Slovakia and Turkey. There are two additional pending applications in China and an additional pending application in each of Brazil, Costa Rica, Ecuador, Egypt, Europe, Eurasia, Hong Kong, Philippines, Singapore, Thailand and Uzbekistan, all projected to expire in 2032, in each case without accounting for any available patent term adjustments or extensions.

A fifth family covering VLP compositions and methods of use contains a U.S. patent application projected to expire in 2039, without accounting for any available patent term adjustments or extensions. There is a pending application in each of Argentina, Australia, Brazil, Canada, China, Colombia, Europe, Hong Kong, Indonesia, Israel, India, Republic of Korea, Mexico, Malaysia, New Zealand, Singapore and Thailand, all projected to expire in 2039, in each case without accounting for any available patent term adjustments or extensions.

A sixth family covering VLP compositions and methods of use contains a U.S. patent application projected to expire in 2039, without accounting for any available patent term adjustments or extensions. There is an additional pending application in Europe, projected to expire in 2039, without accounting for any available patent term adjustments or extensions.

The term of individual patents in our portfolio depends upon the legal term of patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the term of a patent may be eligible for patent term adjustment, which permits patent term restoration as compensation for delays incurred at the USPTO during the patent prosecution process. In addition, for patents that cover an FDA-approved drug, the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, permits a patent term extension of up to five years beyond the expiration of the patent. While the length of the patent term extension is related to the length of time the drug is under regulatory review, patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per approved drug may be extended, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek any available patent term extension to any issued patents we may be granted in any jurisdiction where such extensions are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. The relevant patent laws and their interpretation outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or vaccine candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe, misappropriate or violate our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our licensed pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us or Takeda in the future will be commercially useful in protecting our products or the methods of use or manufacture of those products. Moreover, issued patents do not guarantee the right to practice our technology in

relation to the commercialization of our products. Issued patents only allow us to block potential competitors from practicing the claimed inventions of the issued patents.

Further, patents and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing HIL-214 and any future vaccine candidates and practicing our proprietary technology, and any issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for HIL-214 and any future vaccine candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to HIL-214 and any future vaccine candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular vaccine candidate can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us, and for employees and consultants to enter into invention assignment agreements with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Where applicable, the agreements provide that all inventions to which the individual contributed as an inventor shall be assigned to Hillevax, and as such, will become our property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information. For information regarding the risks related to intellectual property, see "Risk factors—Risks related to our intellectual property."

Further, we have filed for three trademark applications in the United States for the HilleVax trademark and logo.

License agreement with Takeda

On July 2, 2021, we and Takeda entered into the Takeda License. Pursuant to the Takeda License, Takeda granted us: (a) an exclusive, royalty-bearing, sublicensable (with Takeda's reasonable consent) license under (1) certain patents and know-how relating to HIL-214 (formerly TAK-214), and owned or controlled by Takeda during the term of the Takeda License and (2) Takeda's rights in intellectual property jointly created by the parties under the Takeda License (the Joint Intellectual Property), in each case, to commercialize for all human uses worldwide outside of Japan (the Territory) any pharmaceutical products (the Products) containing the HIL-214 compounds and any derivatives thereof to prevent or minimize disease and/or infections caused by norovirus (the Compounds), and (b) a worldwide, non-exclusive, sublicensable (with Takeda's reasonable consent) license under such patents and know-how to develop and manufacture the Compounds and Products solely to: (1) exploit the Compounds and Products in the Territory, (2) perform certain development activities in Japan, and (3) supply the Product to Takeda pursuant to any clinical supply or commercial supply agreement. We granted Takeda: (a) a non-exclusive, fully paid-up, royalty-free, sublicensable license under our rights in any patents and know-how and our rights in the Joint Intellectual Property that are necessary or useful to enable Takeda to develop and manufacture the Compounds and Products anywhere in the world for the purposes of commercialization of the Products in Japan, (b) an exclusive, royalty-bearing, sublicensable license under such patents and know-how to (1) commercialize Products in Japan and (2) commercialize Products for purposes other than for use in humans, and (c) an exclusive, sublicensable license to use Product trademarks solely for commercialization of a Product for human uses in Japan. Certain rights granted to us under the Takeda License are subject to rights granted by Takeda to the United States government pursuant to sponsored research, clinical development and material transfer agreements.

If, other than due to force majeure or our failure to perform our obligations under the Takeda License, Takeda fails to pursue regulatory or commercialization activities by specified deadlines, and does not dispute such failure or initiate such activities by a specified deadline, then the Territory may be expanded to include Japan (i.e., worldwide). During the term of the Takeda License, neither party is permitted to commercialize any vaccine product (other than the Product) that includes norovirus virus-like particles and is being developed for or is approved for the prevention or minimization of symptoms caused by norovirus infections without the other party's prior written consent. We will be responsible, at our cost, for the development, manufacture and commercialization of the Product in the Territory. We are obligated to use commercially reasonable efforts to develop and commercialize the Product in the Territory, and to seek regulatory approval for the Product throughout the world.

We paid Takeda upfront consideration consisting of 840,500 shares of common stock and a warrant to purchase 5,883,500 shares of common stock (the Takeda Warrant). We further agreed that, in the event that Takeda's fully-diluted

ownership, including the Takeda Warrant, represents less a certain specified percentage of our fully-diluted capitalization, including shares issuable upon conversion of outstanding convertible promissory notes, calculated immediately prior to the closing of our initial public offering (IPO), we would issue an additional warrant to purchase shares of common stock such that Takeda would hold a certain specified percentage of the fully-diluted capitalization immediately before the closing of the IPO (the Takeda Warrant Right). The Takeda Warrant was fully exercised in November 2022. The Takeda Warrant Right expired without effect since no fair value had been allocated to it upon completion of our IPO, and no additional warrant was issued. We also paid Takeda a cash payment of $2.5 million upon the consummation of our convertible promissory note financing in August 2021 and paid Takeda $2.5 million in March 2022 upon release of certain drug products and completion of certain regulatory activities. We are required to make to Takeda a one-time payment of $7.5 million upon achievement of a specified development milestone and one-time commercial milestone payments of up to $150.0 million in the aggregate if certain annual sales targets for Products are met in the Territory. We agreed to pay Takeda tiered high-single digit to low-teen percentage royalties on net sales of Products in the Territory, subject to specified offsets and reductions, and Takeda agreed to pay us tiered mid-single digit to low-double digit percentage royalties on net sales of Products in Japan, subject to specified offsets and reductions. Royalties will be payable, on a Product-by-Product and country-by-country basis beginning on the first commercial sale of such Product in such country, until the later of (i) the expiration of the licensed patents covering the applicable Product, (ii) the expiration of regulatory exclusivity in such country, or (iii) 20 years following the first commercial sale of such Product in such country.

Absent early termination, the Takeda License expires on a country-by-country and Product-by-Product basis upon the expiration of the applicable royalty term with respect to each Product in each country, as applicable, or in its entirety upon the expiration of the royalty term with respect to the last Product commercialized in the last country. We may terminate the Takeda License in its entirety without cause upon six months' prior written notice. We and Takeda may terminate the Takeda License in the case of the other party's insolvency, or upon prior written notice within a specified time period for the other party's material uncured breach. Takeda may terminate the Takeda License in its entirety if we challenge the licensed patents, or if we assist any third party in challenging such patents. Upon termination of the Takeda License, Takeda will have an exclusive, transferable, fully paid-up, royalty-free, sublicensable license under the patents and know-how we license to Takeda under the Takeda License and our rights in the Joint Intellectual Property to exploit the Product in the terminated countries.

Transitional services agreement with Takeda

As contemplated by the Takeda License, on December 17, 2021, we and Takeda entered into a Transitional Services Agreement (the TSA). Pursuant to the TSA, Takeda has agreed to provide, on a transitional basis following the effective date of the Takeda License, certain services related to research and development and regulatory assistance services, oversight and management of ongoing clinical and research studies, and maintenance of certain third party vendor contracts. In consideration for the services provided under the TSA, we have agreed to pay certain specified amounts to Takeda in cash for such services and certain pass-through costs.

Unless earlier terminated under its terms, the TSA will remain in effect until all transitional services are completed. We may terminate the provision of any or all services under the TSA upon certain written notice. We and Takeda may terminate the TSA in the case of the other party's insolvency, or upon prior written notice within a specified time period for the other party's material uncured breach. Takeda may terminate the TSA for non-payment and, in certain circumstances, upon a change of control of our company.

Government regulation and product approval

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. biologics regulation

In the United States, biological products, or biologics, such as vaccines are subject to regulation under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other federal, state, local and foreign statutes and regulations. The process required by the FDA before biologics may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice requirements (GLPs);

- submission to the FDA of an IND, which must become effective before clinical trials may begin;
- approval by an institutional review board (IRB) or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended use;
- preparation of and submission to the FDA of a biologics license application (BLA), after completion of all pivotal clinical trials and other necessary studies;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practice requirements (GCPs); and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

The preclinical developmental stage generally involves laboratory evaluations of chemistry, formulation and stability, as well as studies to evaluate the product candidate's toxicity in animals, in an effort to support subsequent clinical testing. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations.

Prior to beginning the first clinical trial with a product candidate in the United States, the trial sponsor must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational biologic to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product candidate, chemistry, manufacturing, and controls information, and any available human data or literature to support the use of the product candidate. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring subject safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study, and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or on other grounds, such as failure to

demonstrate efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries, including clinicaltrials.gov.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. 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 investigational product is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or sponsors may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may also be made a condition to approval of the BLA.

In addition, during the development of a new biologic, sponsors are given opportunities to meet with the FDA at certain points, including prior to submission of an IND, at the end of Phase 2, and before a BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach alignment on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the product candidate.

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

BLA submission and review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product candidate for one or more indications. The BLA must include all relevant data available from preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product candidate, or from a number of alternative sources, including studies initiated by independent investigators. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

In addition, the Pediatric Research Equity Act (PREA), requires a sponsor to conduct pediatric clinical trials for most drugs and biologics, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original BLAs and certain supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the candidate is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must

send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether the product candidate is safe, pure and potent for the proposed indication, and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may also convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will typically 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 and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter (CRL). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the BLA identified by the FDA and may require additional clinical data, including additional clinical trials, or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the BLA or, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may include limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy (REMS), to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy implemented to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety, purity and potency after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited development and review programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the fast track program is intended to expedite or facilitate the process for reviewing product candidates that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product application may be eligible for priority review. A fast track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance

beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a biologic product candidate submitted to the FDA for approval, including a product candidate with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review. A BLA is eligible for priority review if the product candidate is designed to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, depending on the design of the applicable clinical trials, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit, and may require that such studies be underway before granting any accelerated approval. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product candidate 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.

Post-approval requirements

Biologics are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of 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. There also are continuing, annual program fees for any marketed products. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements up. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw 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 restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;

- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims that are in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict a manufacturer's communications on the subject of off-label use of their products.

Biosimilars and reference product exclusivity

The Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product.

Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

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

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of all existing exclusivity protection or patent terms, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Other U.S. regulatory requirements

In addition to FDA regulation of pharmaceutical products, pharmaceutical companies are also subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business and may constrain the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing authorization. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, and transparency laws and regulations related to drug pricing and payments and other transfers of value made to physicians and other healthcare providers. If their operations are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and imprisonment.

Coverage and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of HIL-214 or any potential future vaccine candidate for which we may seek regulatory approval. Sales in the United States will depend, in part, on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs

such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for HIL-214 or any potential future vaccine candidates can be subject to challenge, reduction or denial by third-party payors.

Certain ACA marketplace and other private payor plans are required to include coverage for certain preventative services, including vaccinations recommended by the ACIP without cost share obligations (i.e., co-payments, deductibles or co-insurance) for plan members. Children through 18 years of age without other health insurance coverage may be eligible to receive such vaccinations free-of-charge through the CDC's Vaccines for Children program. For Medicare beneficiaries, vaccines may be covered under either the Part B or Part D program depending on several criteria, including the type of vaccine and the beneficiary's coverage eligibility. If our vaccine candidates, once approved, are covered only under the Part D program, physicians may be less willing to use our products because of the claims adjudication costs and time related to the claims adjudication process and collection of co-payments associated with the Part D program.

The process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. In the United States, there is no uniform policy among payors for coverage or reimbursement. Decisions regarding whether to cover any of a product, the extent of coverage and the amount of reimbursement to be provided are made on a plan-by-plan basis. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that can require manufacturers to provide scientific and clinical support for the use of a product to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Third-party payors may not consider HIL-214 or our potential future vaccine candidates to be medically necessary or cost-effective compared to other available therapies. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval.

In some foreign countries, the proposed pricing for a product candidate must be approved before it may be lawfully marketed. The requirements governing product pricing vary widely from country to country. For example, in the European Union (EU) pricing and reimbursement of pharmaceutical products are regulated at a national level under the individual EU member states' social security systems. Some foreign countries provide options to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and can control the prices and reimbursement levels of medicinal products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A country may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Even if approved for reimbursement, historically, product candidates launched in some foreign countries, such as some countries in the EU, do not follow price structures of the United States and prices generally tend to be significantly lower.

Healthcare reform

In the United States, there have been, and continues to be, legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the profitable sale of product candidates, and similar healthcare laws and regulations exist in the EU and other jurisdictions. Among policy makers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

By way of example, in March 2010, the Patient Protection and Affordable Care Act (the ACA) was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA, among other things, increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or

importers who sell certain “branded prescription drugs” to specified federal government programs; implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded eligibility criteria for Medicaid programs; creates a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, executive and political challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court’s decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the other healthcare reform measures will impact our business.

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, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price (AMP). More recently, on August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

Similar political, economic and regulatory developments are occurring in the EU and may affect the ability of pharmaceutical companies to profitably commercialize their products. On December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment (HTA) amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing

non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Data privacy and security laws

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Foreign regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical studies, marketing authorization and any commercial sales and distribution of our product candidates. The foreign regulatory approval process includes all of the risks associated with FDA approval set forth above, as well as additional country-specific regulation. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product candidates in those countries. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country and can involve additional testing beyond that required by FDA, and may be longer or shorter than that required for FDA approval. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Preclinical studies and clinical trials

Similar to the United States, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls.

Preclinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Preclinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice (GLP) as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, - e.g., radio pharmaceutical precursors for radio-labeling purposes). In particular, preclinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for preclinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceutical for Human Use (ICH), guidelines on good clinical practices (GCP) as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

Certain countries outside of the United States, including the EU, have a similar process that requires the submission of a clinical study application (CTA) much like the IND prior to the commencement of human clinical studies.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation (CTR), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for the member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the EU Clinical Trials Directive required a separate CTA to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and the IRB, respectively, the CTR introduces a centralized process and only requires the submission of a single

application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state.

The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each countries with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with good manufacturing practice (GMP). Other national and EU-wide regulatory requirements may also apply.

Marketing authorizations

In order to market our product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal products candidates can only be placed on the market after obtaining a marketing authorization (MA). To obtain regulatory approval of an investigational biological product under EU regulatory systems, we must submit a MA application (MAA). The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs:

- "Centralized MAs" are issued by the European Commission through the centralized procedure based on the opinion of the European Medicines Agency's (EMA) Committee for Human Medicinal Products (CHMP), and are valid throughout the EU. The centralized procedure is compulsory for human medicines that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) designated orphan medicines and (iv) advanced therapy medicinal products (ATMPs), such as gene therapy, somatic cell therapy or tissue-engineered medicines. The centralized procedure may at the request of the applicant also be used in certain other cases.
- "National MAs" are issued by the competent authorities of the EU member states and only cover their respective territory, and are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the national competent authority of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

Under the centralized procedure, the maximum timeframe for the evaluation of a MAA by the EMA is 210 days, excluding clock stops. In exceptional cases, the CHMP might perform an accelerated review of a MAA in no more than 150 days (not including clock stops). Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIiority MEdicine (PRIME) scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is not guaranteed. The benefits of a PRIME designation include, but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Moreover, in the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring

increased safety measures. It is valid for one year and has to be renewed annually until fulfillment of all the conditions. Once the pending studies are provided, it can become a “standard” MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA ceases to be renewed. Furthermore, MA may also be granted “under exceptional circumstances” when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This MA is close to the conditional MA as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA “under exceptional circumstances” is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

Under the above described procedures, in order to grant the MA, the EMA or the competent authorities of the EU member states make an assessment of the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. Standard MAs have an initial duration of five years. After these five years, the authorization may be renewed for an unlimited period on the basis of a reevaluation of the risk-benefit balance.

Data and marketing exclusivity

The EU also provides opportunities for market exclusivity. For example, in the EU, upon receiving MA, new products authorized for marketing (i.e., reference products) generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the EU from referencing the innovator’s data to assess a generic or biosimilar application during a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two year period of market exclusivity, a generic/biosimilar MA can be submitted, and the innovator’s data may be referenced, but no generic/biosimilar product can be marketed until the expiration of the market exclusivity. The overall ten-year market exclusivity period may be extended to a maximum of eleven years if, during the first eight years of those ten years, a new therapeutic indication with significant clinical benefit over existing therapies is approved. However, there is no guarantee that a product will be considered by the EU’s regulatory authorities to be a new chemical or biological entity, and products may not qualify for data exclusivity.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Pediatric Development

In the EU, MAAs for new medicinal products have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan (PIP) agreed with the EMA’s Pediatric Committee (PDCO). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all the EU member states and study results are included in the product information, even when negative, the product is eligible for six months’ supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan pharmaceutical products, a two year extension of the orphan market exclusivity is granted.

Foreign post-approval requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance (QPPV) who is responsible for the establishment and maintenance of that system, and

oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (PSURs).

All new MAA must include a risk management plan (RMP) describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

The aforementioned EU rules are generally applicable in the European Economic Area (EEA), which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Human Capital Resources

As of December 31, 2023, we had 90 full-time employees. Of these employees, 28 hold a M.D. or Ph.D. degree, and 60 were engaged in research and development. None of our team members are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

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

Corporate Information

We were originally founded as a Delaware corporation on March 25, 2020 under the name MokshaCo, Inc. On February 8, 2021, we changed our name to HilleVax, Inc. and merged with North Bridge V, Inc. and YamadaCo III, Inc., each of which were Delaware corporations, with HilleVax, Inc. as the surviving entity. Our principal executive offices are located at 321 Harrison Avenue, Boston, Massachusetts 02118, and our telephone number is (617) 213-5054.

Available Information

Our website address is www.hillevax.com, and our investor relations website is located at www.ir.hillevax.com. We will make available on our website, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. They are also available for free on the SEC's website at www.sec.gov.

We use our investor relations website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Investors should monitor such website, in addition to following our press releases, SEC filings and public conference calls and webcasts. Information relating to our corporate governance is also included on our investor relations website. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information included in this Annual Report, including our financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before making an investment decision to purchase or sell shares of our common stock. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose part or all of your investment. The risks described below are not the only ones that we may face, and additional risks or uncertainties not known to us or that we currently deem immaterial may also impair our business, future prospects, operations and financial condition. In this section, we first provide a summary of the principal risks and uncertainties we face and then provide a full set of risk factors and discuss them in greater detail.

Summary of Risks Related to Our Business

The risk factors included below are a summary of the principal risk factors associated with an investment in us. The summary below does not contain all of the risks we face. You should carefully consider this summary, together with the more detailed discussion of these risks and uncertainties in the following section.

- We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.
- We currently depend entirely on the success of HIL-214, which is our only vaccine candidate in clinical development. If we are unable to advance HIL-214 in clinical development, obtain regulatory approval and ultimately commercialize HIL-214, or experience significant delays in doing so, our business will be materially harmed.
- Clinical and preclinical development involves a lengthy and expensive process with an uncertain outcome, and the results of prior clinical trials and studies of HIL-214 are not necessarily predictive of our future results. We have not completed any clinical trials for HIL-214 and we may not have favorable results in our clinical trials, or receive regulatory approval on a timely basis, if at all.
- Any difficulties or delays in the commencement or completion, or the termination or suspension, of our ongoing and planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- Use of HIL-214 or any other vaccine candidates could be associated with adverse side effects, adverse events or other safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a vaccine candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.
- We rely heavily on the Takeda License to provide us intellectual property rights to develop and commercialize HIL-214. If the Takeda License is terminated, we would lose our rights to develop and commercialize HIL-214.
- We rely on third parties to conduct many of our clinical trials and preclinical studies and to manufacture HIL-214, and these third parties may not perform satisfactorily which could delay, prevent or impair our development efforts or ability to seek or obtain regulatory approval for HIL-214.
- We face significant competition, and if our competitors develop technologies or vaccine candidates more rapidly than we do or their technologies are more effective, our business and our ability to develop and successfully commercialize products may be adversely affected.
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.
- If we are unable to obtain, maintain and enforce patent protection for HIL-214 or any other vaccine candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize HIL-214 or any other vaccine candidates may be adversely affected.

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

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2019, and we have no products approved for clinical commercial sale. To date, we have focused primarily on organizing and staffing our company, business planning, raising capital, in-licensing intellectual property related to our initial vaccine candidate, HIL-214, and preparing for our ongoing and planned clinical trials of HIL-214. We have not yet submitted an IND or its equivalent to any applicable regulatory agencies or completed any clinical trials, manufactured a commercial-scale product or arranged for a third party to do so on our behalf, obtained regulatory approvals, or conducted sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they would be if we had a history of successfully developing and commercializing vaccines.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical-stage biopharmaceutical companies in rapidly evolving fields. If our ongoing and planned clinical trials are successful, we will also need to transition from a company with a research focus to a company capable of successfully executing drug development activities and supporting commercial operations. If we do not adequately address these risks and difficulties or successfully make such a transition, our business, financial condition, results of operations and prospects will be significantly harmed.

We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

We have incurred significant operating losses since our inception. We do not have any products approved for sale and have not generated any revenue since our inception. If HIL-214 is not successfully developed, approved and commercialized, we may never generate any revenue. Our net losses were $123.6 million and $159.8 million for the years ended December 31, 2023 and 2022, respectively. We have financed our operations to date through the issuance of convertible promissory notes, commercial bank debt, the proceeds from our IPO, and the proceeds from our underwritten public offering. Substantially all of our losses have resulted from expenses incurred in connection with in-licensing intellectual property related to, and developing, HIL-214 and from general and administrative costs associated with our operations. HIL-214 and any other vaccine candidate, including HIL-216, will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for and potentially commercialize HIL-214 and seek to identify, assess, acquire, in-license intellectual property related to or develop additional vaccine candidates.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of HIL-214, HIL-216 and any other vaccine candidates, obtaining regulatory approval for these vaccine candidates, and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may have an adverse effect on the value of our company and could impair our ability to raise

capital, expand our business, maintain our research and development efforts, diversify our vaccine candidates or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.

The development of vaccine candidates is capital-intensive. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned clinical trials for HIL-214 and potentially seek regulatory approval for HIL-214 and potentially initiate clinical development of HIL-216 and any other vaccine candidates we may develop. In addition, if we are able to progress HIL-214 through development and commercialization, we will be required to make milestone and royalty payments to Takeda, from which we have in-licensed certain patents and know-how related to HIL-214 globally, other than in Japan, pursuant to the license agreement we entered into with Takeda on July 2, 2021 (the Takeda License), and with respect to HIL-216, will be required to make milestone and royalty payments to Kangh under our exclusive license agreement (the Kangh License). If we obtain regulatory approval for HIL-214 or any other vaccine candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reliably estimate the actual amounts necessary to successfully complete the development and commercialization of HIL-214 or any other vaccine candidates. Furthermore, we expect to incur additional costs associated with operating as a public company. We do not have any committed external source of funds.

Based on our current operating plan, we believe that our existing cash and cash equivalents will enable us to fund our operations for at least the next 12 months. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect and need to seek additional funds sooner than planned. Our existing cash and cash equivalents will not be sufficient to complete development of HIL-214, or any other vaccine candidate, and we will require substantial capital in order to advance HIL-214 and any other vaccine candidates through clinical trials, regulatory approval and commercialization. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We expect to finance our cash needs through public or private equity or debt financings or other capital sources, including potential collaborations, licenses, non-dilutive sources of financing, such as grants, and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop HIL-214 and any other vaccine candidates.

Our future capital requirements will depend on many factors, including, but not limited to:

- the initiation, type, number, scope, results, costs and timing of, our ongoing and planned clinical trials of HIL-214 and preclinical studies or clinical trials of HIL-216 or other potential vaccine candidates we may choose to pursue in the future, including any modifications to clinical development plans based on feedback that we may receive from regulatory authorities;
- the costs and timing of manufacturing for HIL-214, or any other vaccine candidates, and placebo to be used in our trials, as well as commercial scale manufacturing, if any vaccine candidate is approved;
- the costs, timing and outcome of regulatory meetings and reviews of HIL-214 or other vaccine candidates;
- any delays and cost increases that may result from any epidemic diseases, such as the COVID-19 pandemic, including any associated supply chain disruption and staffing shortages;
- the costs of obtaining, maintaining, enforcing and protecting our patents and other intellectual property and proprietary rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development and commercial personnel;
- the terms and timing of establishing and maintaining collaborations, license agreements and other similar arrangements;

- the timing and amount of the milestone, royalty or other payments we must make to Takeda and any future licensors;
- the costs and timing of establishing or securing sales and marketing capabilities if HIL-214 or any other vaccine candidates are approved;
- our ability to receive recommendations from the ACIP, or other foreign national immunization technical advisory groups (NITAGs), and achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- vaccine recipients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors; and
- costs associated with any products or technologies that we may in-license or acquire.

Conducting preclinical studies and clinical trials 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 regulatory approval and commercialize HIL-214 and any other vaccine candidates. If approved, HIL-214 and any other vaccine candidates may not achieve commercial success. Our commercial revenue, if any, will initially be derived from sales of HIL-214, which we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, including as a result of financial and credit market deterioration or instability, market-wide liquidity shortages, geopolitical events or otherwise.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, our loan and security agreement with Hercules Capital, Inc., as administrative and collateral agent, and the lenders party thereto, debt financings, or other capital sources, including potential collaborations, license agreements and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. The Loan Agreement includes, and any future debt financing and preferred equity financing, if available, may involve agreements that include, covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through future collaborations, license agreements and other similar arrangements, we may be required to relinquish valuable rights to our future revenue streams, research programs, vaccine candidates, intellectual property or proprietary technology, or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market vaccine candidates that we might otherwise prefer to develop and market ourselves.

Risks Related to the Development and Regulatory Approval of Our Vaccine Candidates

We currently depend entirely on the success of HIL-214, which is our most advanced vaccine candidate. If we are unable to advance HIL-214 in clinical development, obtain regulatory approval and ultimately commercialize HIL-214, or experience significant delays in doing so, our business will be materially harmed.

We currently only have one vaccine candidate in clinical development, HIL-214, the intellectual property for which we have in-licensed from Takeda and which is in Phase 2 clinical development. Our business presently depends entirely on our ability to successfully develop, obtain regulatory approval for, and commercialize HIL-214 in a timely manner. This may make an investment in our company riskier than similar companies that have multiple vaccine candidates in active development that may be able to better sustain the delay or failure of a vaccine candidate. In addition, our assumptions about HIL-214's development potential are based in large part on the data generated from preclinical studies and clinical trials conducted by Takeda and Ligocyte and we may observe materially and adversely different results as we conduct our ongoing and planned clinical trials. The success of HIL-214, as well as HIL-216 and any other vaccine candidates, will depend on several factors, including the following:

- acceptance by the FDA, the European Medicines Agency (EMA) or other comparable foreign regulatory authorities of our proposed design of our planned clinical trials, as well as our proposed immunobridging strategy to additional subject populations;

- successful initiation and enrollment of clinical trials and completion of clinical trials with favorable results;
- successful completion of preclinical studies with favorable results, including toxicology and other studies designed to be compliant with good laboratory practices (GLP);
- successful development and qualification of a number of clinical assays to support the determination of our primary and secondary endpoints and the performance of such clinical assays in such trials;
- demonstrating the safety, purity, potency, immunogenicity and efficacy of HIL-214 and any other vaccine candidates to the satisfaction of applicable regulatory authorities;
- making arrangements with third-party manufacturers for, or establishing, manufacturing capabilities for the clinical and, if approved, commercial supply of HIL-214 and any other vaccine candidates;
- receipt of marketing approvals from applicable regulatory authorities, including approvals of biologics license applications (BLAs) or supplements from the FDA and similar marketing authorization applications (MAAs) from the European Commission, and maintaining such approvals;
- establishing sales, marketing and distribution capabilities and launching commercial sales of HIL-214, if and when approved, whether alone or in collaboration with others;
- obtaining, establishing and maintaining patent and trade secret protection or regulatory exclusivity for HIL-214;
- maintaining an acceptable safety profile of HIL-214 and any other vaccine candidates following regulatory approval, if any;
- maintaining and growing an organization of people who can develop and, if approved, commercialize, market and sell HIL-214 and any other vaccine candidates; and
- acceptance of our products, if approved, by patients, the medical community and third-party payors.

In addition, our development plan for HIL-214 initially targets the prevention of moderate to severe AGE caused by norovirus in infants. Depending on the feedback we receive from regulatory agencies, we may decide to further limit our initial target population to a subset of infants, such as infants with certain underlying health conditions common within this age range, or we may materially modify our current plans to use immunobridging studies based on a serology surrogate endpoint and or the criteria proposed to seek subsequent regulatory authorizations in older children, adults and older adults. Limiting our target patient population may negatively impact our ability to complete clinical trials or studies within our planned timeline and could limit the commercial potential of HIL-214. If we are unable to develop, receive marketing approval for and successfully commercialize HIL-214 or any other vaccine candidate in our targeted patient populations, or if we experience delays as a result of any of the above factors or otherwise, our business would be significantly harmed.

Clinical and preclinical development involves a lengthy and expensive process with an uncertain outcome, and the results of prior clinical trials and studies of HIL-214 are not necessarily predictive of our future results. We have not completed clinical trials for HIL-214 and we may not have favorable results in our clinical trials, or receive regulatory approval on a timely basis, if at all.

Clinical and preclinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any preclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the trial or study process. For example, we may not be able to meet expected timeframes for the enrollment of our ongoing Phase 2b clinical trial of HIL-214 or the reporting of data from such trial. Despite promising preclinical or clinical results, any vaccine candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for vaccine candidates in our industry is high, particularly in the early stages of development.

The results from preclinical studies or clinical trials of a vaccine candidate or a competitor's vaccine candidate in the same class may not predict the results of later clinical trials of such vaccine candidate, and interim, topline, or preliminary results of a clinical trial are not necessarily indicative of final results. Vaccine candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. In particular, while HIL-214 has been studied by Takeda in an extensive clinical program that included nine clinical trials, we do not know how HIL-214 will perform in our ongoing and planned clinical trials, whether due to design differences, subject population or otherwise, including our use of a different manufacturing process to produce clinical material than that used in these prior trials. For these reasons and others, it is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials. Many vaccine candidates fail in clinical trials despite very promising early results, and a number of companies in the biopharmaceutical and biotechnology industries

have suffered significant setbacks in clinical development even after achieving promising results in earlier preclinical studies and clinical trials. Based upon negative or inconclusive results, we or any future collaborator may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, which would cause us to incur additional operating expenses. Further, since there are no reliable animal models to norovirus infection, we may have to complete additional human challenge studies, which have been used to understand viral activity and possible immune correlates that prevent infection, making trials costlier than animal-based studies.

In addition, under the Takeda License, Takeda, a third party over which we have no control, has the right to develop and commercialize HIL-214 in Japan. If Takeda conducts any clinical trials of HIL-214 or if such trials generate negative results or results that conflict with the results of our clinical trials, the FDA or other regulatory authorities may delay, limit, or deny approval of HIL-214, require us to conduct additional clinical trials as a condition to marketing approval, or withdraw their approval of HIL-214 or otherwise restrict our ability to market and sell HIL-214, if approved. We face similar risks with respect to Kangh's rights to develop this candidate in Greater China under the Kangh License.

As a result, we cannot be certain that our ongoing and planned preclinical studies and clinical trials will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of HIL-214 in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation (CTR) which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application (CTA) to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as contract research organizations (CROs), may impact our developments plans.

Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.

Before obtaining marketing approval from regulatory authorities for the sale of HIL-214 or any other vaccine candidates, we must conduct extensive clinical trials to demonstrate the safety, purity, potency, immunogenicity and efficacy of the vaccine candidates in humans. In September 2021, an open IND was transferred to us by Takeda, under which we initiated a Phase 2b clinical trial. Before we can initiate clinical trials for HIL-216 or any other vaccine candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about vaccine candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND with the FDA or as part of any similar regulatory submission required for allowance to proceed with clinical development. The FDA, EMA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies, or added clinical evaluation under any IND, clinical trial application or similar regulatory submission, which may lead to delays and increase the costs of our clinical development program. Moreover, even if we commence clinical trials, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion of our ongoing and planned clinical trials for HIL-214, HIL-216 and any other vaccine candidates could significantly affect our product development timelines and product development costs.

We do not know whether our planned clinical trials will begin on time or be completed on schedule, if at all. The commencement, data readouts and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtaining regulatory authorizations or allowances to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA, EMA or comparable foreign regulatory authorities disagreeing as to the implementation of our clinical trials;
- any failure or delay in reaching an agreement with contract research organizations (CROs) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- obtaining approval from one or more institutional review boards (IRBs) or ethics committees at clinical trial sites;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- major changes or amendments to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with good clinical practice (GCP) requirements or applicable regulatory guidelines in other countries;
- manufacturing sufficient quantities of HIL-214 and placebo for use in clinical trials, which could be materially impacted by the COVID-19 outbreaks, supply chain disruption or other issues;
- expiration of the shelf life of clinical material for use in clinical trials prior to the enrollment of any of our clinical trials;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials due to movement restrictions, heath reasons or otherwise resulting from an outbreak of a highly infectious or contagious disease;
- insufficient incidence of norovirus infection to allow us to evaluate the endpoints in our clinical trials of HIL-214;
- individuals choosing an alternative product for the indication for which we are developing HIL-214 or any other vaccine candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or serious unexpected vaccine-related adverse effects;
- occurrence of vaccine-related serious adverse events in trials of other protein-based vaccine candidates conducted by other companies that could be considered similar to HIL-214 or any other vaccine candidates;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization (CMO), delays or failure by our CMOs or us to make any necessary changes to such manufacturing process, or failure of our CMOs to produce clinical trial materials in accordance with current good manufacturing practice (cGMP) regulations or other applicable requirements; and
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a vaccine, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to

comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we are and plan to do for HIL-214 and may do for HIL-216 and other vaccine candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, relevant to such foreign countries.

In addition, many of the factors that cause, or lead to, the termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a vaccine candidate. We may make formulation or manufacturing changes to HIL-214 or any other vaccine candidates, in which case we may need to conduct additional preclinical studies to bridge our modified vaccine candidates to earlier versions. Any resulting delays to our clinical trials could shorten any period during which we may have the exclusive right to commercialize our vaccine candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of HIL-214 or any other vaccine candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects.

We may find it difficult to enroll subjects in our clinical trials. If we encounter difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Successful and timely completion of clinical trials will require that we identify and enroll a specified number of subjects for each of our clinical trials. We may not be able to initiate or continue clinical trials for HIL-214, HIL-216 or any other vaccine candidates if we are unable to identify and enroll a sufficient number of eligible subjects to participate in these trials as required by the FDA or similar regulatory authorities outside the United States.

Subject enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the subject population, the severity of the disease under investigation, the proximity of subjects to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the ability to obtain and maintain informed consents, the ability to co-administer a vaccine candidate with other vaccines, the risk that enrolled subjects will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, and competing clinical trials and clinicians' and subjects' perceptions as to the potential advantages and risks of the vaccine candidate being studied in relation to other available vaccines or therapies, including any new products that may be approved for the indications we are investigating as well as any vaccine candidates under development.

Specifically for our planned Phase 3 trial of HIL-214, we believe the convenience of potentially co-administrating HIL-214 with other pediatric vaccines may be an important factor in timely enrolling subjects into the trial. We plan to conduct a Phase 2 trial to evaluate the immune response to routine pediatric vaccinations when co-administered with HIL-214 or placebo. This trial will be designed to gather data to help support potential co-administration in our planned Phase 3 trial. An inability to co-administer HIL-214 in our planned Phase 3 trial may negatively affect enrollment.

We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

As an organization, we have never completed any clinical trials, and we may be unable to do so for HIL-214 or any other vaccine candidates.

We will need to successfully complete our planned clinical trials in order to seek FDA or comparable foreign regulatory approval to market HIL-214 or any other vaccine candidates. Carrying out clinical trials and the submission of a successful BLA or MAA is a complicated process. We initiated a Phase 2b clinical trial of HIL-214 in infants in May 2022. Takeda previously conducted both Phase 1 and 2 clinical trials of HIL-214, and we have not previously completed any clinical trials. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that enables us to seek and maintain approval of HIL-214 or any other vaccine candidates. We may require more time and incur greater costs than Takeda required, or than our competitors require, and may not succeed in obtaining regulatory approvals of vaccine candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting BLAs or MAAs for and potentially commercializing HIL-214 or any other vaccine candidates.

Use of HIL-214 or any other vaccine candidates could be associated with adverse side effects, adverse events or other safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a vaccine candidate, limit the commercial profile of an approved label or result in other significant

negative consequences that could severely harm our business, prospects, operating results and financial condition.

As is the case with biopharmaceuticals generally, it is likely that there may be adverse side effects associated with HIL-214 or any other vaccine candidates' use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of expected or unexpected side effects. Vaccine-related side effects could affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Undesirable side effects caused by our vaccine candidates when used alone or in combination with approved drugs, biologics or vaccines could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or lead to the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Any of these occurrences could severely harm our business, prospects, operating results and financial condition.

Moreover, if HIL-214 or any other vaccine candidates are associated with undesirable side effects in clinical trials or demonstrate characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the vaccine candidate if approved. We may also be required to modify our development and clinical trial plans based on findings after we commence clinical trials. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compounds. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

In addition to our ongoing Phase 2b clinical trial in infants and planned Phase 3 clinical trials, we will need to conduct co-administration trials with other vaccines as required to fit into a pediatric vaccination schedule, as well as other required pediatric trials. It is possible that as we test HIL-214 or any other vaccine candidates in larger, longer and more extensive clinical trials, or if the use of these vaccine candidates becomes more widespread following regulatory approval, more illnesses, injuries, discomforts and other adverse events than were observed in earlier trials, as well as new conditions that did not occur or went undetected, may be discovered. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly. Further, if a serious safety issue is identified in connection with use of HIL-214 in any trials that may be conducted by Takeda, such issues may adversely affect the development potential of HIL-214 or result in regulatory authorities restricting our ability to develop HIL-214.

In addition, if HIL-214 or any other vaccine candidate receives marketing approval, and we or others later identify undesirable side effects caused by such vaccine, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approvals of such vaccine or seek an injunction against its manufacture or distribution;
- we may be required to recall a vaccine or change the way such vaccine is administered to individuals;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy (REMS) or create a medication guide outlining the risks of such side effects for distribution to individuals;
- we may be required to change the way a vaccine is distributed or administered, conduct additional clinical trials or change the labeling of a vaccine or be required to conduct additional post-marketing studies or surveillance;
- we could be sued and held liable for harm caused to vaccine recipients;
- sales of the vaccine may decrease significantly or the vaccine could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular vaccine candidate, if approved, and could significantly harm our business, results of operations and prospects.

Vaccine candidates are subject to extensive regulation and compliance, which is costly and time consuming, and such regulation and compliance may cause unanticipated delays or prevent the receipt of the required approvals and licenses to commercialize HIL-214 and any other vaccine candidates.

The clinical development, manufacturing, labeling, packaging, storage, record-keeping, advertising, promotion, import, export, marketing, distribution and adverse event reporting, including the submission of safety and other information, of vaccine candidates are subject to extensive regulation by the FDA in the United States, the EMA in the European Union

(EU) and by comparable foreign regulatory authorities in other foreign markets. In the United States, we are not permitted to market our vaccine candidates until we receive regulatory approval from the FDA in the United States, which is referred to as licensure. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the vaccine candidates involved, as well as the target indications and populations. Approval policies or regulations may change, and the FDA and the EMA have substantial discretion in the vaccine approval process, including the ability to delay, limit or deny approval of a vaccine candidate for many reasons. Despite the time and expense invested in clinical development of vaccine candidates, regulatory approval is never guaranteed. We are not permitted to market any of our vaccine candidates until we receive approval of a BLA from the FDA in the United States or a MAA by the European Commission in the EU.

Prior to obtaining approval to commercialize a vaccine candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities, that such vaccine candidates are safe, pure and potent and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our vaccine candidates are promising, such data may not be sufficient to support approval by the FDA or comparable foreign regulatory authorities. The FDA, EMA or other comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for HIL-214 or any other vaccine candidates either prior to approval or post-approval, or may object to elements of our clinical development program.

The FDA or other comparable foreign regulatory authorities can delay, limit or deny approval of a vaccine candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials, or results may not otherwise meet the level of statistical significance required by the FDA, EMA or other comparable foreign regulatory agencies for approval;
- serious and unexpected vaccine-related side effects may be experienced by participants in our clinical trials or by individuals using vaccines similar to our vaccine candidates;
- such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from those of their respective home countries;
- we may be unable to demonstrate that a vaccine candidate is safe and effective, and that such vaccine candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our vaccine candidates are acceptable or sufficient to support the submission of a BLA, MAA or other marketing application, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling and/or the specifications of HIL-214 or any other vaccine candidates;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or be subject to other significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes, approval policies or facilities of Takeda and any other third-party manufacturers with which we contract for clinical and commercial supplies;
- regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval; or
- such authorities may not accept a submission due to, among other reasons, the content of or presentation of the data in the submission.

Of the large number of vaccines and biologics in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market HIL-214 and any other vaccine candidates, which would significantly harm our business, results of operations and prospects.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition,

events raising questions about the safety of certain marketed biopharmaceuticals may result in increased cautiousness by the FDA, EMA and other comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals.

Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing HIL-214 or any other vaccine candidates.

We may not be successful in our efforts to investigate HIL-214 in additional age groups or in additional indications and formulations. We may expend our limited resources to pursue a particular indication or formulation for HIL-214 and fail to capitalize on vaccine candidates, indications or formulations that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific vaccine candidates, development programs and indications. We plan to focus our initial development efforts on evaluating HIL-214 for the prevention of moderate-to-severe acute gastroenteritis caused by norovirus in infants. We then plan to pursue an immunobridging strategy to expand the development of HIL-214 to older children, adults, older adults and other high-risk groups. Immunobridging studies aim to demonstrate non-inferiority of immune response against a pre-specified criteria between a reference age group (i.e., infants) and target age groups in specific clinical trials. These studies require an appropriate and acceptable serological surrogate and assay and are designed to support supplemental or additional marketing authorization for other age groups without the need for an efficacy trial. However, we may not be able to confirm an appropriate serological surrogate in our infant efficacy trials and even if we do, the FDA, EMA or other comparable foreign regulatory authority may not support our proposed immunobridging criteria or strategy. If either of these events occur, we would be required to conduct additional efficacy clinical trials in adults, which would lead to significant delays and would materially increase the costs of our clinical development program for HIL-214 in these additional age groups. We may also evaluate alternative formulations or combinations of HIL-214, including through the addition of new norovirus strains to cover relevant or emerging genotypes, as well as additional vaccine candidates such as HIL-216. As a result of our decision to pursue a given age group, formulation or indication, or particular vaccine candidate, we may forgo or delay pursuit of opportunities with other vaccine candidates that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and vaccine candidates for specific indications may not yield any commercially viable vaccine candidates. If we do not accurately evaluate the commercial potential or target market for a particular vaccine candidate, we may relinquish valuable rights to that vaccine candidate through collaborations, license agreements and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such vaccine candidate.

If the incidence rates of infection for the specific pathogens we are targeting are smaller than we believe they are, our clinical development may be adversely affected, and our business may suffer.

Our projections of both the number of people who have a norovirus infection, as well as the subset of people with genotypes who have the potential to benefit from treatment with HIL-214 and any other vaccine candidates, are based on our estimates. These estimates have been derived from a variety of sources, including scientific literature, epidemiologic surveys, and market research based on healthcare databases, and may prove to be incorrect or imprecise. In addition, precise incidence for the noroviruses we aim to address with HIL-214 and any other vaccine candidates may vary from season to season. Further, new trials or information may change the estimated incidence of these diseases. Our planned clinical trial sizes are based on our current estimates for rates of infection for the specific norovirus targeted by HIL-214, and such rates and estimates may have been affected by the COVID-19 pandemic and resulting changes in social interactions and behaviors. If our estimates are incorrect, this may impact the number of subjects that need to be recruited for our clinical trials, the time required to evaluate trial endpoints in these subjects and the overall time to complete the trial, may result in us having to repeat a clinical trial, or could impact the likelihood of success of our clinical development.

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

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data

we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular vaccine candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, HIL-214 and any other vaccine candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Changes in methods of vaccine candidate manufacturing or formulation may result in additional costs or delay.

As vaccine candidates progress through clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize safety, efficacy, yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. For example, the manufacturing process being used to produce clinical material for our ongoing and planned clinical trials is different than that used in prior trials of HIL-214. These changes and any future changes we may make to HIL-214 or any other vaccine candidates may cause such candidates to perform differently and affect the results of future clinical trials conducted with the altered materials. Such changes or negative trial results could delay initiation or completion of clinical trials, require the conduct of bridging studies or clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay potential marketing approval and jeopardize our ability to commercialize HIL-214 or any other vaccine candidates, if approved, and generate revenue.

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

The ability of the FDA, other government agencies and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency's ability to perform routine functions. Average review times at the FDA, other government agencies and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to approved biologics to be reviewed and/or approved by necessary government or foreign regulatory agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA resumed standard inspection operations of any resurgence of the virus or emergence of new variants may lead to further inspectional or administrative delays. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the

ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Our Reliance on Third Parties

We heavily rely on the Takeda License to provide us with intellectual property rights to develop and commercialize HIL-214. If the Takeda License is terminated, we would lose our rights to develop and commercialize HIL-214.

Pursuant to the Takeda License, we have, among other things, secured an exclusive license from Takeda under certain patents and know-how relating to HIL-214 to commercialize HIL-214 globally, with the exception of Japan. The Takeda License expires on a country-by-country basis and product-by-product basis upon the expiration of the applicable royalty term with respect to each product in each country, as applicable, or in its entirety upon the expiration of the royalty term with respect to the last product commercialized in the last country, unless terminated earlier. We may terminate the Takeda License in its entirety without cause upon six months' prior written notice. We and Takeda may terminate the Takeda License in the case of the other party's insolvency, or upon prior written notice within a specified time period for the other party's material uncured breach. Takeda may terminate the Takeda License in its entirety if we challenge the licensed patents, or if we assist any third party in challenging such patents. In addition, if any of the regulatory milestones or other cash payments become due under the terms of the Takeda License, we may not have sufficient funds available to meet our obligations, Takeda has the right to terminate the Takeda License upon our uncured failure to pay Takeda. If the Takeda License is terminated, we would lose our rights to develop and commercialize HIL-214, which in turn would have a material adverse effect on our business, operating results and prospects. We face similar risks with respect to our rights to HIL-216 under the Kangh License.

We rely on third parties to conduct preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize HIL-214 and any other vaccine candidates may be delayed.

We depend on third parties to conduct our preclinical studies and clinical trials for HIL-214 and any other vaccine candidates. Specifically, we rely on, and will continue to rely on, medical institutions, clinical investigators, CROs and consultants to conduct preclinical studies and clinical trials, in each case in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. Though we expect to carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, while we will have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the applicable protocol and legal, regulatory and scientific standards and requirements, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities. In addition, we and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for HIL-214 and any other vaccine candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Furthermore, our clinical trials must be conducted with vaccine candidates and placebo produced under cGMP and similar foreign regulations. Failure to comply with these regulations may require us to repeat clinical trials or recall batches of our vaccine candidate or placebo, which would delay the regulatory approval process.

There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to our preclinical studies or clinical trials or perform as contractually required. If any of these third parties fails to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting preclinical studies, clinical trials or other development activities that could harm our competitive position.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we work to carefully manage our relationships with our

CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We currently rely on third parties for the manufacture of HIL-214 for clinical development and expect to continue to rely on third parties for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of HIL-214 or such quantities at an acceptable cost, which could delay, prevent or impair our development or potential commercialization efforts.

We do not own or operate manufacturing facilities and have no plans to develop our own clinical or commercial-scale manufacturing capabilities. Pursuant to the Takeda License, we entered into a clinical manufacturing and supply agreement with Takeda for the supply of HIL-214 for our Phase 2b clinical trial in infants. We also will rely on Kangh for the supply of HIL-216 for use in our near-term clinical trials. We also rely, and expect to continue to rely, on additional third-party manufacturers for the manufacture of HIL-214, placebo, critical reagents and related raw materials for clinical development, as well as for commercial manufacture if HIL-214, HIL-216 or any other vaccine candidate receives marketing approval. The facilities used by third-party manufacturers to manufacture our vaccine candidates must be approved for the manufacture of such candidate by the FDA and any comparable foreign regulatory authority pursuant to inspections that will be conducted after we submit a BLA to the FDA or any comparable submission to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP and similar foreign requirements for manufacture of products. In addition, we have no control over the ability of third-party manufacturers to procure raw material supplies and maintain adequate quality control, quality assurance and qualified personnel. Furthermore, the process of manufacturing biologics is complex and highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of our third-party manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely affect our business. Further, our clinical supply of HIL-214, HIL-216 and placebo for use in future clinical trials has a shelf life that may expire prior to the full enrollment of our ongoing and planned clinical trials causing similar delays or other supply disruptions. Any performance failure on the part of our third-party manufacturers could delay clinical development or marketing approval of HIL-214 or any other vaccine candidate, and may adversely affect our future profit margins and our ability to commercialize any vaccines that receive marketing approval on a timely and competitive basis.

In addition, we do not have any long-term commitments or long-term supply agreements with any third-party manufacturers. We may be unable to establish any supply agreements with additional third-party manufacturers or to do so on acceptable terms, which increases the risk of failing to timely obtain sufficient quantities of HIL-214 or such quantities at an acceptable cost. Even if we are able to establish long-term agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications, our schedule, or at all;
- infringement, misappropriation or other violation of our intellectual property and proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us, and HIL-214 and any other vaccine candidates that we may develop may compete with other vaccine candidates and products for access to such manufacturers and manufacturing facilities. Increased competition amongst developers to access manufacturers and materials could increase the costs of, or otherwise limit our ability to, manufacture HIL-214 or any other vaccine candidates.

If materials manufactured by our third-party manufacturers do not conform to our specifications or the regulatory requirements necessary for use in clinical trials, we may experience delays in our development efforts or may

need to find alternative manufacturing facilities, which would significantly impact our ability to obtain regulatory approval for or commercialize our vaccine candidates, if approved.

Our third-party manufacturers may be unable to successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority. In order for us to use the material manufactured by third-party manufacturers, their manufacturing facilities in which our materials are produced must comply with applicable laws and regulations governing the manufacture of biologic product candidates, and upon a request for marketing authorization, these facilities must be authorized for the manufacture of HIL-214 and any other vaccine candidates in connection with any approval of a marketing application we submit. If the FDA or any comparable foreign regulatory authority determines that such facilities are noncompliant or does not authorize these facilities to manufacture our vaccine candidates or if it withdraws any such authorization in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our vaccine candidates, if approved. While we are seeking to identify and secure additional third-party contract manufacturers, we may be unable to do so at an acceptable cost, or at all, which could significantly impact our ability to obtain regulatory approval for or commercialize HIL-214, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of vaccine candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Additionally, our third-party manufacturers may rely on single source suppliers for certain of the raw materials for our preclinical and clinical product supplies. If current or future suppliers are delayed or unable to supply sufficient raw materials to manufacture product for our preclinical studies and clinical trials, we may experience delays in our development efforts as materials are obtained or we locate and qualify new raw material manufacturers.

Our or a third party's failure to execute on our manufacturing requirements on commercially reasonable terms and in compliance with cGMP or other regulatory requirements could adversely affect our business in a number of ways, including:

- an inability to initiate clinical trials of HIL-214 or any other vaccine candidates;
- delay in submitting regulatory applications, or receiving marketing approvals, for HIL-214 or any other vaccine candidates;
- subjecting third-party manufacturing facilities or our potential future manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of HIL-214 or any other vaccine candidates; and
- in the event of approval to market and commercialize HIL-214 or any other vaccine candidates, an inability to meet commercial demands for such vaccines.

Any performance failure on the part of Takeda or other future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time consuming to implement. In addition, our current and anticipated future dependence upon others for the manufacture of HIL-214 and any other vaccine candidates may adversely affect our future profit margins and our ability to commercialize any vaccines that receive marketing approval on a timely and competitive basis.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover them or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on third parties to manufacture HIL-214 and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors or other third parties, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor's or other third party's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure of such technology or information would

impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

We may seek to enter into collaborations, license agreements and other similar arrangements and may not be successful in doing so, and even if we are, we may relinquish valuable rights and may not realize the benefits of such relationships.

We may seek to enter into collaborations, joint ventures, license agreements and other similar arrangements for the development or commercialization of HIL-214 and any other vaccine candidates, due to capital costs required to develop or commercialize the vaccine candidate or manufacturing constraints. We may not be successful in our efforts to establish or maintain such collaborations because our research and development pipeline may be insufficient, HIL-214 or any other vaccine candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view such vaccine candidates as having the requisite potential to demonstrate safety, immunogenicity and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time-consuming and complex.

Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us. For example, we may need to relinquish valuable rights to our future revenue streams, research programs, intellectual property or vaccine candidates, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential collaborators. In addition, if we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our vaccine candidates. Our ability to generate revenue from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a collaboration, license or strategic transaction, we will achieve an economic benefit that justifies such transaction. Furthermore, we may not be able to maintain such collaborations if, for example, the development or approval of a vaccine candidate is delayed, the safety of a vaccine candidate is questioned or the sales of an approved vaccine candidate are unsatisfactory.

Collaborations involving HIL-214 or any other vaccine candidates would pose significant risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not pursue development and commercialization of any vaccine candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a vaccine candidate, repeat or conduct new clinical trials or require a new formulation of a vaccine candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, vaccines that compete directly or indirectly with our vaccine candidates if the collaborators believe that competitive vaccines are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- vaccine candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own vaccine candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our vaccine candidates;
- a collaborator with marketing and distribution rights to any vaccine candidate that achieves regulatory approval may not commit sufficient resources to the marketing and distribution of such vaccines;
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays in or termination of the research, development or commercialization of vaccine candidates, might lead to additional responsibilities for us with respect to vaccine candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly enforce, maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborators may not provide us with timely and accurate information regarding development, regulatory or commercialization status or results, which could adversely impact our ability to manage our own development efforts, accurately forecast financial results or provide timely information to our stockholders regarding our out-licensed vaccine candidates;
- we may be required to invest resources and attention into such collaboration, which could distract from other business objectives;
- disputes may arise between the collaborators and us regarding ownership of or other rights in the intellectual property generated in the course of the collaborations;
- collaboration agreements may not lead to development or commercialization of vaccine candidates in the most efficient manner or at all;
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated; and
- collaborations may be terminated, including for the convenience of the collaborator, prior to or upon the expiration of the agreed upon terms and, if terminated, we may find it more difficult to enter into future collaborations or be required to raise additional capital to pursue further development or commercialization of the applicable vaccine candidates.

Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to HIL-214 or any other vaccine candidates, could delay the development and commercialization of such vaccine candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Commercialization of HIL-214 and Any Other Vaccine Candidates

Even if we receive regulatory approval for HIL-214 and any other vaccine candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, HIL-214 and any other vaccine candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our vaccine candidates, when and if any of them are approved.

Any regulatory approvals that we may receive for HIL-214 or any other vaccine candidates will require the submission of reports to regulatory authorities, subject us to surveillance to monitor the safety and efficacy of the product, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS as a condition of approval of HIL-214 or any other vaccine candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves HIL-214 or any other vaccine candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and similar foreign requirements, and GCP requirements for any clinical trials that we conduct post-approval. Failure to comply with regulatory requirements or later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- fines, restitutions, disgorgement of profits or revenue, warning letters, untitled letters, adverse publicity requirements or holds on clinical trials;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize HIL-214 or any other vaccine candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any vaccine candidates we develop. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

In addition, FDA and foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may, however, have a significant impact on the pharmaceutical industry and our business in the long term.

HIL-214 and any other vaccine candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (the ACA), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, the FDA may approve a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. We believe that HIL-214 or any other vaccine candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our vaccine candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated.

The commercial success of HIL-214 or any other vaccine candidates will depend upon the degree of market acceptance of such vaccine candidates by healthcare providers, vaccine recipients, healthcare payors and others in the medical community, which is reliant on a number of factors, including the receipt of a preferred recommendation from the ACIP or other foreign national immunization technical advisory groups.

HIL-214 and any other vaccine candidates may not be commercially successful. Even if HIL-214 or any other vaccine candidates receive regulatory approval, they may not gain market acceptance among healthcare providers, individuals within our target population, healthcare payors, NITAGs or the medical community. The commercial success of any of HIL-214 or any other vaccine candidates will depend significantly on the broad adoption and use of the resulting product by these individuals and organizations for approved indications. The degree of market acceptance of our products will depend on a number of factors, including:

- demonstration of clinical efficacy and safety;
- the indications for which our vaccine candidates are approved;

- any anti-vaccine sentiments within our targeted patient population;
- the limitation of our targeted population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a competing vaccine for the relevant indication by healthcare providers and their patients;
- acceptance of, and preference for, a therapeutic that treats the condition our vaccine targets, by healthcare providers and their patients;
- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- receiving recommendations from the ACIP or other foreign NITAGs for use, as well as placement of our vaccine candidates on national immunization programs, which may impact the likelihood of third-party coverage and extent of healthcare provider acceptance;
- the willingness of pediatricians and healthcare professionals generally to recommend that patients receive our vaccine;
- the willingness of vaccine recipients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of our products as well as competitive drugs;
- the effectiveness of our sales and marketing strategies; and
- unfavorable publicity relating to the product.

In the United States, the ACIP develops vaccine recommendations, and there are similar NITAG agencies in other jurisdictions around the world that develop vaccine recommendations. To develop its recommendations, the ACIP forms working groups that gather, analyze and prepare scientific information. The ACIP also considers many of the factors above, as well as myriad additional factors such as the value of vaccination for the target population regarding the outcomes, health economic data and implementation issues. The ACIP recommendations are also made within categories, such as in an age group or a specified risk group, and vaccines that receive a preferred ACIP recommendation are generally widely adopted in the United States. Following completion of our Phase 2b and 3 clinical trials of HIL-214 in infants, if achieved, ACIP may decline to recommend our vaccine. In addition, the failure of any other developer of norovirus vaccine candidates to secure such an ACIP recommendation, or any limitations of any ACIP recommendations secured by any other developers, may limit the market opportunity of HIL-214 or any other vaccine candidates. If HIL-214 or any other vaccine candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product and may not become or remain profitable.

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

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about biologics. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion.

Any regulatory approval that the FDA grants is limited to those indications and patient populations for which a biologic product is deemed to be safe, pure and potent by the FDA. While physicians in the United States may choose, and are generally permitted, to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the FDA, our ability to promote HIL-214 and any other vaccine candidates, if approved, will be narrowly limited to those indications and populations that are specifically approved by the FDA, and if we are found to have promoted such off-label uses, we may become subject to significant liability. For example, the federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is

changed or curtailed. If we cannot successfully manage the promotion of HIL-214 or any other vaccine candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

The successful commercialization of HIL-214 or any other vaccine candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most vaccine recipients to be able to afford prescription medications such as HIL-214 and any other vaccine candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved vaccine candidate. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require copayments that vaccine recipients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available, or at an acceptable level, for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new vaccines will be covered. Some third-party payors may require pre-approval of coverage for new or innovative products before they will reimburse healthcare providers who use such products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for HIL-214 and any other vaccine candidates. In addition, certain ACA marketplace and other private payor plans are required to include coverage for certain preventative services, including vaccinations recommended by the ACIP and on the CDC's National Immunization Program, without cost share obligations (i.e., co-payments, deductibles or co-insurance) for plan members. Children up to 18 years of age without other health insurance coverage may be eligible to receive such vaccinations free-of-charge through the CDC's Vaccines for Children program. For Medicare beneficiaries, vaccines may be covered for reimbursement under either Medicare Part B or Part D depending on several criteria, including the type of vaccine and the beneficiary's coverage eligibility. If HIL-214 or any other vaccine candidates, if approved, are reimbursed only under the Part D program, healthcare providers may be less willing to use our products because of the claims adjudication costs and time related to the claims adjudication process and collection of co-payment associated with the Part D program.

Obtaining and maintaining reimbursement status is time-consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently and, in some cases, at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on

healthcare costs in general, and prescription drugs, surgical procedures and other treatments in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

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

Our industry is characterized by rapid advancing technologies, intense competition and a strong emphasis on proprietary and novel products. The current vaccine market is concentrated among a few global biopharmaceutical companies including BioNTech, CSL Bering, GlaxoSmithKline, Merck, Moderna, Pfizer, Sanofi, and Takeda, which together account for the majority of global vaccine sales. Other pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions are also active in the vaccine market given the continuing global need for both existing and new vaccines. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. Any vaccine candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing intellectual property related to new vaccine candidates. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

There are currently no approved vaccines for the prevention of norovirus-related illness. While we are not aware of all of our competitors' efforts, based on public statements, we believe that several companies are in various stages of developing a vaccine for norovirus-related illness, including China National Biotec, Chongqing Zhifei Biological, Icon Genetics, Moderna and Vaxart. We believe that China National Biotec, Chongqing Zhifei Biological and Icon Genetics are also focused on developing a vaccine consisting of VLPs representing the GI and GII genogroups of norovirus. Further, we believe that China National Biotec and Chongqing Zhifei Biological are also developing a pediatric vaccine for the prevention of norovirus-related illness.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for HIL-214 or any other vaccine candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered, the extent to which vaccine recipients accept relatively new vaccines, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competing products may render HIL-214 or any other vaccine candidates we develop obsolete or noncompetitive before we recover the expense of developing and commercializing such vaccine candidate. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may need to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If HIL-214 or any other vaccine candidates ultimately receives regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time-consuming. Alternatively, we may need to collaborate with third parties that have direct sales forces and established distribution systems, in lieu of or to augment our own sales force and distribution systems. We plan to independently commercialize HIL-214, if approved, in the United States by building a highly-targeted sales force to support the adoption of HIL-214 and we plan to seek one or more partners with existing commercial infrastructure and expertise in markets outside the United States. We have no prior experience as a company with the marketing, sale or distribution of biopharmaceutical products and there are significant risks involved in the building and managing of a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenue and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and

market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize HIL-214 and any other vaccine candidates in foreign markets, particularly Europe. We are not permitted to market or promote any vaccine candidate before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for HIL-214 or any other vaccine candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of HIL-214 and any other vaccine candidates. Approval procedures may be more onerous than those in the United States and may require that we conduct additional preclinical studies or clinical trials. If we obtain regulatory approval of vaccine candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- pricing pressure from vaccine procurement organizations;
- determinations by NITAGs not to include our vaccine products in immunization schedules for our target patient populations;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- compliance with export control and import laws and regulations;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- differing regulatory requirements with respect to manufacturing of vaccine products;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires; and
- disruptions resulting from the impact of public health pandemics or epidemics (including, for example, the COVID-19 pandemic).

Risks Related to Our Business Operations and Industry

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

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

- the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to HIL-214, HIL-216 or any other vaccine candidates, which may change from time to time;

- the timing and success or failure of preclinical studies or clinical trials for HIL-214, HIL-216 or any other vaccine candidates or competing vaccine candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- coverage and reimbursement policies with respect to HIL-214 or any other vaccine candidates, if approved, and potential future drugs that compete with our products;
- the cost of manufacturing HIL-214 or any other vaccine candidates, which may vary depending on the quantity of production and the terms of our agreements with Takeda, Kangh and any future third-party manufacturers;
- the timing and amount of the milestone, royalty or other payments we will be required to pay to Takeda pursuant to the Takeda License or Kangh under the Kangh License;
- expenditures that we may incur to acquire, develop or commercialize additional vaccine candidates and technologies;
- the level of demand for any approved products, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies; and
- changes in general market and economic conditions.

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

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

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, as well as our senior scientists and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our vaccine candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As of December 31, 2023, we had 90 full-time employees, including 60 employees engaged in research and development. As we continue development and pursue the potential commercialization of our vaccine candidates, as well as transition to functioning as a public company, we will need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. In addition, we may need to expand our facilities, including laboratory operations, and may be unable to do so on commercially reasonable terms, or at all. Our future financial performance and our ability to

develop and commercialize HIL-214 and any other vaccine candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

The terms of our Loan Agreement place restrictions on our operating and financial flexibility.

On April 18, 2022, we entered into a Loan and Security Agreement (Loan Agreement) with Hercules Capital, Inc., as administrative and collateral agent, and the lenders party thereto, providing for term loans of up to $75.0 million in the aggregate (collectively, Term Loans). We borrowed $5.0 million on April 18, 2022, $10.0 million on December 15, 2022, and an additional $10.0 million on June 16, 2023. We have the right to borrow an additional $50.0 million in the aggregate subject to the achievement of certain specified financing and clinical development milestones (as described in the section titled "Management's discussion and analysis of financial condition and results of operations—Liquidity and capital resources—Term Loan Facility") and no event of default having occurred and be continuing. All obligations under the Term Loans are secured by a first priority lien on substantially all of our assets, including intellectual property and certain other assets. As a result, if we default on any of our obligations under the Loan Agreement, the lenders could foreclose on their security interest and liquidate some or all of the collateral, which would harm our business, financial condition and results of operations and could require us to reduce or cease operations.

In order to service this indebtedness and any additional indebtedness we may incur in the future, we need to generate cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. Our business may not be able to generate sufficient cash flow from operations, and future borrowings or other financings may not be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This could place us at a competitive disadvantage compared to our competitors that have less indebtedness.

The Loan Agreement contains certain customary affirmative and negative covenants and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding our operating accounts. The negative covenants include, among others, limitations on our ability to incur additional indebtedness and liens, merge with other companies or consummate certain changes of control, acquire other companies or businesses, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements, including the Takeda License, or enter into various specified transactions.

While we believe we are currently in compliance with the covenants contained in the Loan Agreement, we may breach these covenants in the future. Our ability to comply with these covenants may be affected by events and factors beyond our control. In the event that we breach one or more covenants, the lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding under the Loan Agreement, terminate any commitment to extend further credit and foreclose on the collateral. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations.

We are subject to various U.S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our results of operations and financial condition.

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

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

causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS), information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives), teaching hospitals and other healthcare providers, as well as ownership and investment interests held by physicians, as defined by statute, and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biotechnology companies to report information on the pricing of certain drug products; and some state and local laws that require the registration or pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including consulting agreements with certain physicians who are paid in the form of stock or stock options as compensation for services provided to us, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize HIL-214 and any other vaccine candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell HIL-214 and any other vaccine candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the ACA was enacted in the United States. The ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed

care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the Public Health program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; created a new Medicare Part D coverage gap discount program; established a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS 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, and on June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden had issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the healthcare reform measures of the Biden administration will impact our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for products. At the federal level, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's AMP. Most recently, on August 16, 2022, the IRA was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for HIL-214 and any other vaccine candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We expect that the ACA, these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize HIL-214 and any other vaccine candidates, if approved.

Similar political, economic and regulatory developments are occurring in the EU and may affect the ability of pharmaceutical companies to profitably commercialize their products. On December 13, 2021, Regulation No 2021/2282

on Health Technology Assessment (HTA) amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

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

We face an inherent risk of product liability as a result of the ongoing and planned clinical trials of HIL-214 and any other vaccine candidates and will face an even greater risk if we commercialize such vaccine candidates. For example, we may be sued if HIL-214 or any other vaccine candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the vaccine candidate, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, vaccine recipients or others using, administering or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of our management's time and our resources;
- substantial monetary awards to trial participants or vaccine recipients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact;
- the inability to commercialize HIL-214 or any other vaccine candidates; and
- a decline in our stock price.

We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of HIL-214 or any other vaccine candidates. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of HIL-214 or any other vaccine candidates. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, workers' compensation, clinical trials, and directors' and officers', employment practices and fiduciary liability insurance. We do not know, however, if we will be able to maintain insurance with

adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

We and any of our potential future collaborators will be required to report to regulatory authorities if any of our approved products cause or contribute to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.

If we or any of our potential future collaborators are successful in commercializing our products, the FDA and foreign regulatory authorities would require that we and such collaborators report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We and any of our potential future collaborators or CROs may fail to report adverse events within the prescribed timeframe. If we or any of our current or potential future collaborators or CROs fail to comply with such reporting obligations, the FDA or a foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

We and our service providers may be subject to a variety of data privacy and security laws, regulations, standards, and contractual obligations, which could increase compliance costs, and our actual or perceived failure to comply could subject us to potentially significant liability, fines or penalties and otherwise harm our business.

We and our service providers maintain and will maintain a large quantity of sensitive information, including confidential business and patient health information, in connection with our preclinical studies and clinical trials, and are subject to laws and regulations governing the privacy and security of such information. The global data protection landscape is rapidly evolving, and we and our service providers may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. These laws and regulations may be subject to differing interpretations, which adds to the complexity of processing personal information. Guidance on implementation and compliance practices are often updated or otherwise revised. This may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer, use, share and otherwise process personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, numerous federal and state laws and regulations, including health information privacy laws, data breach notification laws and consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, storage, transfer, disclosure, protection and other processing of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party providers. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

In addition, certain state laws govern the privacy and security of health-related and other personal information in certain circumstances. These laws are evolving rapidly and may differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. By way of example, the California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020, gives California residents individual privacy rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability and many similar laws have been proposed at the federal level and in other states. Further, the California Privacy Rights Act (CPRA) passed in California and imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions of the CPRA went into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in other states, and continue to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. In

the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

There also are a wide variety of privacy laws in other countries that may impact our operations, now or in the future. For example, in Europe, the General Data Protection Regulation (GDPR) imposes stringent requirements regarding the collection, use, disclosure, storage, transfer or other processing of personal data of individuals within the European Economic Area (EEA) or in the context of our activities taking place within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions). Among other requirements, the GDPR regulates the transfer of personal data from the EEA to the United States and other jurisdictions that the European Commission does not recognize as having “adequate” data protection laws. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the European Union (“CJEU”) states that reliance on the standard contractual clauses - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On October 7, 2022, President Biden signed an Executive Order on 'Enhancing Safeguards for United States Signals Intelligence Activities' which introduced new redress mechanisms and binding safeguards to address the concerns raised by the CJEU in relation to data transfers from the EEA to the United States and which formed the basis of the new EU-US Data Privacy Framework (“DPF”), as released on December 13, 2022. The European Commission adopted its Adequacy Decision in relation to the DPF on July 10, 2023, rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. The DPF also introduced a new redress mechanism for EU citizens which addresses a key concern in the previous CJEU judgments and may mean transfers under standard contractual clauses are less likely to be challenged in future. We currently rely on the EU standard contractual clauses and the UK Addendum to the EU standard contractual clauses as relevant to transfer personal data outside the EEA and the UK, including to the United States, with respect to both intragroup and third party transfers. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, following the withdrawal of the United Kingdom from the European Union and the EEA and the end of the transition period, from January 1, 2021, we have had to comply with the GDPR and separately the GDPR as implemented in the United Kingdom, which, together with the amended UK Data Protection Act 2018 (collectively, the "UK GDPR"), retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR and has the ability to fine up to the greater of €20 million/£17 million or 4% of global turnover. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a UK GDPR data transfer mechanism to U.S. entities self-certified under the UK Extension to the DPF. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

In many jurisdictions, enforcement actions and consequences for noncompliance are rising. In the United States, these include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us. If we fail to follow these security standards, even if no personal information is compromised, we may incur significant fines or experience a significant increase in costs.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, store, use, transfer, disclose and otherwise process data, update our data privacy and security policies and procedures, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators and our service providers to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers

who share this information with us, may contractually limit our ability to use and disclose such information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and adversely affect our business, financial condition, results of operations and prospects. Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our information technology systems, or those of any of our service providers, may fail or suffer security breaches, loss or leakage of data and other disruptions, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are increasingly dependent upon information technology systems and infrastructure to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to 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.

There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information. Our information technology systems and those of our third-party service providers, strategic partners and other contractors or consultants are vulnerable to attack and damage or interruption from computer viruses and malware (e.g. ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. These attacks can present meaningful risks to our operations, data and commercial information. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who continue to work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

Any security breach or other incident, whether actual or perceived, could impact our reputation and/or operations, cause us to incur significant costs, including legal expenses, subject us to regulatory action or investigation, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We also rely on third parties to manufacture HIL-214, and similar events relating to their information technology systems could also have a material adverse effect on our business. To the extent that any actual or perceived disruption or security breach affects our systems (or those of our third-party collaborators, service providers, contractors or consultants) or were to result in a loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development and commercialization of HIL-214 or any other vaccine candidate could be delayed, and we could be subject to significant fines, penalties or liabilities for any noncompliance to certain privacy and security laws.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. In December 2023, we experienced a security incident resulting from an in-person fraudulent impersonation of an employee which permitted a third party to gain limited access to our systems. We promptly activated incident response protocols, which included shutting down certain systems, and commenced an investigation of the incident. We also notified Federal law enforcement and engaged outside legal counsel and other third-party incident response and cybersecurity professionals, as well as forensic professionals. Based on our assessment, the incident has not had a material impact on us, and we do not believe the incident has materially affected or will materially affect us, including our operations, business strategy, results of operations, or financial condition.

While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or result in the unauthorized disclosure of or access to personally identifiable information or individually identifiable health information, it could result in a material

disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

We have also 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. If our third-party vendors fail to protect their information technology systems and our confidential and proprietary information, we may be vulnerable to disruptions in service and unauthorized access to our confidential or proprietary information and we could incur liability and reputational damage. If the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular categories of personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships and the costs associated with the investigation, remediation and potential notification of the breach to counter-parties and data subjects could be material.

Our business is subject to risks arising from pandemics and other epidemic diseases.

The COVID-19 worldwide pandemic presented substantial public health and economic challenges and affected our employees, clinical trial subjects, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies, financial markets, labor markets and supply chains. Any future pandemic or epidemic disease outbreaks, and any supply chain disruptions or staffing shortages, could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for HIL-214 for use in our clinical trials and research and preclinical studies and, delay, limit or prevent our employees and CROs from continuing research and development activities, impede our clinical trial initiation and recruitment and the ability of subjects to continue in clinical trials, result in a decrease in the incidence of norovirus infection among trial subjects delaying any evaluation of the endpoints in our clinical trials of HIL-214 and the ultimate completion of such trials, including due to measures taken that may limit social interaction or prevent reopening of high-transmission settings, impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our preclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. Any future pandemic or epidemic disease outbreaks could also potentially further affect the business of the FDA or other regulatory authorities, which could result in delays in meetings related to our planned clinical trials.

Our business could be affected by litigation, government investigations and enforcement actions.

We currently operate in a number of jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States. or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings which may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any such proceeding, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations.

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

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, including cGMP requirements, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad or (iv) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical

trials, the creation of fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain and enforce patent protection for HIL-214 or any other vaccine candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize HIL-214 or any other vaccine candidates may be adversely affected.

Our success depends in large part on our ability to obtain, maintain and enforce patent protection in the United States and other countries with respect to our vaccine candidates and other proprietary technologies we may develop. We seek to protect our proprietary position, in part, by exclusively licensing patents and patent applications in the United States and abroad relating to our vaccine candidates, manufacturing processes, and methods of use. If we or our principal licensor, Takeda, are unable to obtain, maintain or enforce patent protection, our business, financial condition, results of operations and prospects could be materially harmed.

Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our or our licensors' ability to protect our intellectual property, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. We cannot predict whether the patent applications we currently or may in the future pursue or in-license will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection against competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we or our licensors may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, third party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our or our licensors' ability to seek patent protection. Consequently, we may not be able to prevent any third party from using any of our technology that is in the public domain to compete with our vaccine candidates and technologies. In addition, our

ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable in light of the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that our licensors were the first to invent the inventions claimed in any of our licensed patents or pending patent applications or patents or pending patent applications we may own in the future, or that we or our licensors were the first to make the inventions claimed in those patents or pending patent applications, or were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patents and patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our owned and in-licensed patent applications or patent applications we may own in the future may not result in patents being issued which protect our vaccine candidates or proprietary technologies we may develop or which effectively prevent others from commercializing competitive technologies and products. In fact, patent applications may not issue as patents at all.

Moreover, the claim coverage in a patent application can be significantly reduced before the corresponding patent is granted. Even if our in-licensed patent applications or patent applications we may own in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Any patents issuing from our in-licensed patent applications may be challenged, narrowed, circumvented or invalidated by third parties. Our competitors or other third parties may avail themselves of safe harbors under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) to conduct research and clinical trials. Consequently, we do not know whether our vaccine development programs and other proprietary technology will be protectable or remain protected by valid and enforceable patents. Even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. In addition, given the amount of time required for the development, testing and regulatory review of our vaccine candidates, patents protecting the vaccine candidates might expire before or shortly after such vaccine candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability and our patent rights may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office (USPTO) challenging the validity of one or more claims of our in-licensed patents or patents we may own in the future. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. A third party may also claim that our patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In addition, we may become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review or interference proceedings and other similar proceedings in foreign jurisdictions challenging the validity, priority or other features of patentability of our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our vaccine candidates and other proprietary technologies we may develop and compete directly with us, without payment to us, or result in our inability to commercialize products without infringing third-party patent rights. Such adverse determinations may also require us to cease using the related technology or to attempt to license rights from the prevailing party. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing, could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, some of our patent rights may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patent rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of such patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We do not own any issued patents or patent applications and we completely depend on intellectual property licensed from third parties, including under the Takeda License, and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are

terminated or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.

We do not own any issued patents or patent applications. Our vaccine candidate is completely dependent on patents, know-how and proprietary technology licensed from Takeda under the Takeda License. As a result, any termination of the Takeda License would result in the loss of significant rights and could harm our ability to commercialize HIL-214. The Takeda License imposes, and we expect that any future license agreements where we in-license intellectual property will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under the Takeda License or future license agreements, or we are subject to bankruptcy-related proceedings, the licensor may have the right to terminate the license, in which event we would not be able to develop or market the products covered by the license, including our HIL-214 vaccine candidate. In addition, we may need to obtain additional licenses from our existing licensors and others to advance our research or allow commercialization of vaccine candidates we may develop. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In either event, we may be required to expend significant time and resources to redesign our technology, vaccine candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology or vaccine candidates. Even if we are able to obtain such additional licenses, they may be non-exclusive thereby giving our competitors and other third parties access to the same technology licensed to us.

If we or our licensors fail to adequately maintain, enforce and protect our licensed intellectual property, our ability to commercialize HIL-214 or any other vaccine candidates could suffer. We do not have complete control over the maintenance, enforcement, prosecution and litigation of our in-licensed patents and patent applications and may have limited control over future intellectual property that may be in-licensed. Therefore, such in-licensed patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. For example, we cannot be certain that activities such as the maintenance and prosecution by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. It is possible that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves, or may not be conducted in accordance with our best interests. Furthermore, there are certain limitations to our right to enforce certain exclusively licensed patents, including, for example, the requirement that we obtain the licensor's consent prior to settling lawsuits related to such patents. If our licensors fail to maintain such patents or patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our vaccine candidates that are the subject of such licensed rights and our right to exclude third parties from commercializing competing products could be adversely affected. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the Takeda License and the Kangh License are, and any future agreements under which we license intellectual property or technology from third parties may be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant patents, know-how and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. In spite of our efforts, our current and future licensors might conclude that we have materially breached our obligations under our license agreements and might therefore terminate such license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. Disputes that may arise between us and our licensors regarding intellectual property subject to a license agreement could include disputes regarding:

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

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on reasonable terms, we may be unable to successfully develop and commercialize the affected technology or vaccine candidates. As a result, any termination of or disputes over our intellectual property licenses could result in the loss of our ability to develop and commercialize HIL-214 or any other vaccine candidates, or we could lose other significant rights, experience significant delays in the development and commercialization of our vaccine candidates, or incur liability for damages, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with our vaccine candidates.

If our licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical or competitive to ours and we may be required to cease our development and commercialization of certain of our vaccine candidates. Moreover, if disputes over intellectual property that we license prevent or impair our ability to maintain other licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected vaccine candidates.

In addition, certain of our agreements may not be assignable by us without the consent of the respective licensor, which may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, if we choose to sublicense or assign to any third parties our rights under the Takeda License with respect to any licensed product, we may be required to wait for a certain period or until the occurrence of certain funding or development milestones.

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

Filing, prosecuting and defending patents on HIL-214 and any other vaccine candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States, or from selling or importing products made using our or our licensors' intellectual property in and into the United States or other jurisdictions. Competitors may use our intellectual property in jurisdictions where we and our licensors have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our owned and in-licensed patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our in-licensed patents, if pursued and obtained, or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, some jurisdictions, such as Europe and China, may have a higher standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our in-licensed patents or patents we may own in the future at risk of being invalidated or interpreted narrowly, could put our in-licensed patent applications or patent applications we may own in the future at risk of not issuing and could provoke third parties to assert claims against us. We or our licensors may not prevail in any lawsuits that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

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

to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some circumstances, we are dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. For example, periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our licensed patents and applications or any patents and applications we may own in the future. In certain circumstances, we rely on our licensors to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The USPTO and various non-U.S. government agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the United States, China, India and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner and the nature of the subject matter to be disclosed (e.g., items related to national security or national defense). In some cases, a foreign filing license may be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. We are also dependent on our licensors to take the necessary actions to comply with these requirements with respect to our licensed intellectual property.

The COVID-19 pandemic may impair our and our licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for our vaccine candidates.

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

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the America Invents Act) enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us or our licensors could therefore be awarded a patent covering an invention of ours or our licensors even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our vaccine candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary

standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our in-licensed patent applications or patent applications we may own in the future and the enforcement or defense of patents issuing from those patent applications, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. We cannot predict how decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patent rights. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Issued patents covering our vaccine candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

Our patent rights may be subject to priority, validity, inventorship and enforceability disputes. If we or our licensors are unsuccessful in any of these proceedings, such patents and patent applications may be narrowed, invalidated or held unenforceable, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or we may be required to cease the development, manufacture and commercialization of HIL-214 or one or other vaccine candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we or our licensors' initiated legal proceedings against a third party to enforce a patent covering our vaccine candidates, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, lack of sufficient written description, failure to claim patent-eligible subject matter or obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patent rights in such a way that they no longer cover our vaccine candidates or prevent third parties from competing with our vaccine candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our vaccine candidates. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect the competitive position of our vaccine candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our vaccine candidates are obtained, once the patent has expired, we may be vulnerable to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new vaccine candidates, patents protecting such vaccine candidates might expire before or shortly after such

vaccine candidates are commercialized. As a result, our in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension and equivalent extensions outside of the United States for our vaccine candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of HIL-214 or any other vaccine candidate we may develop, one or more of our in-licensed issued U.S. patents or issued U.S. patents we may own in the future may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension (PTE) of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate (SPC). However, we may not be granted an extension for various reasons, including failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or failing to satisfy other applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we may need the cooperation of that third party. If we are unable to obtain patent term extension, or the foreign equivalent, or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our patent rights, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our vaccine candidates and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our vaccine candidates and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

In addition to seeking patent protection for our vaccine candidates and proprietary technologies, we also rely on trade secret protection and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, third-party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Trade secrets and know-how can be difficult to protect. We cannot guarantee that we have entered into applicable agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed or misappropriated, or if any such information were to be independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing our vaccine candidate. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to our vaccine

candidates and other proprietary technologies we may develop. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products and vaccine candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we or our licensors have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future products and vaccine candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our vaccine candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover vaccine candidates or the use of our vaccine candidates.

The scope of a patent claim is determined by the interpretation of the law, the words of a patent claim, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products or vaccine candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third-party patent is invalid or unenforceable. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products and vaccine candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our vaccine candidates that are held to be infringing. We might, if possible, also be forced to redesign vaccine candidates or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Some of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

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

Third-party claims of intellectual property infringement, misappropriation or other violations against us or our potential future collaborators could be expensive and time consuming and may prevent or delay the development and commercialization of our vaccine candidates.

Our commercial success depends in part on our ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative

proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including inter partes review and post-grant review have also been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patent rights in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are commercializing or plan to commercialize HIL-214. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that HIL-214 or any other vaccine candidates, and commercializing activities may give rise to claims of infringement of the patent rights of others. We cannot assure you that HIL-214 or any other vaccine candidates will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued for which a third party, such as a competitor in the fields in which we are developing our vaccine candidates, might accuse us of infringing. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we infringe or that we believe we have valid defenses to any claims of patent infringement, could be found to be infringed by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to our vaccine candidates. As such, we monitor third-party patents in the relevant pharmaceutical markets. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that we may infringe.

In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by us. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, we may be required to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. Such licenses may not available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms or at all, we may be unable to commercialize the infringing products or technologies or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. In addition, we may in the future pursue patent challenges with respect to third- party patents, including as a defense against the foregoing infringement claims. The outcome of such challenges is unpredictable.

Even if resolved in our favor, the foregoing proceedings could be very expensive, particularly for a company of our size, and time-consuming. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Such proceedings may also absorb significant time of our technical and management personnel and distract them from their normal responsibilities. Uncertainties resulting from such proceedings could impair our ability to compete in the marketplace. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our patent and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Third parties, such as a competitor, may infringe our patent rights. In an infringement proceeding, a court may decide that a patent owned by us or licensed to us is invalid or unenforceable or may refuse to stop the other party from using the invention at issue on the grounds that the patent does not cover the technology in question. In addition, our or our licensors' patent rights may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time-consuming. An adverse result in any litigation proceeding could put our patent rights at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial

amount of discovery required in connection with intellectual property litigation and proceedings, there is a risk that some of our confidential information could be compromised by disclosure during such litigation and proceedings.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing, misappropriating or violating other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we may propose to use with HIL-214 or any other vaccine candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe, misappropriate or otherwise violate the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to obtain, protect or enforce our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement, misappropriation, dilution or other claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to obtain, enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to HIL-214 or any other vaccine candidates or utilize similar technology but that are not covered by the claims of the patents that we license;
- we or our licensors might not have been the first to make the inventions covered by our or our licensors' current or future patent applications;
- we or our licensors might not have been the first to file patent applications covering our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our or our licensors' technologies without infringing our intellectual property rights;
- it is possible that our or our licensors' current or future patent applications will not lead to issued patents;

- any patent issuing from our or our licensors' current or future patent applications may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- others may have access to the same intellectual property rights licensed to use in the future on a non-exclusive basis;
- our competitors or other third parties might conduct research and development activities in countries where we or our licensors do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents or other intellectual property rights of others may harm our business; and
- we may choose not to file for patent protection in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property.

Should any of the foregoing occur, it could adversely affect our business, financial condition, results of operations and prospects.

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

The growth of our business may depend in part on our ability to acquire, in-license or use third-party intellectual property and proprietary rights. For example, HIL-214 or any other vaccine candidates may require specific formulations to work effectively and efficiently and we may develop vaccine candidates containing our compounds and pre-existing pharmaceutical compounds, which could require us to obtain rights to use intellectual property held by third parties. For example, we may find from our preclinical or clinical trials that HIL-214 or any other vaccine candidates achieve improved efficacy through combination with proprietary adjuvants. We may not be able to achieve long-term access to these adjuvants or may be only able to do so under unfavorable terms. This could limit the effectiveness of HIL-214 or any other vaccine candidates if we are unable to obtain access to these adjuvants or could impact our potential profitability if we can only obtain access under unfavorable terms. In addition, with respect to any patent or other intellectual property rights we may co-own with third parties, we may require licenses to such co-owners interest to such patents. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe, misappropriate or otherwise violate those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we may collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize HIL-214 or any other vaccine candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional vaccine candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business financial condition, results of operations and prospects could suffer.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies.

Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

We have in-licensed certain patents and patent applications that have been generated through the use of U.S. government funding or grants, and we may acquire or license in the future additional intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. Many of the U.S. patents and patent applications that we currently license that may be subject to these government rights are licensed from Takeda pursuant to the Takeda License and relate to HIL-214. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third-party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). If the U.S. government exercises its march-in rights in our current or future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. Any exercise by the government of such rights or failure by us to comply with federal regulations regarding intellectual property rights that were developed through the use of U.S. government funding could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Our Common Stock

An active, liquid and orderly market for our common stock may not be maintained.

We can provide no assurance that we will be able to maintain an active trading market for our common stock. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

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

Our stock price is likely to be volatile. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price at which they paid. The market price for our common stock may be influenced by the factors discussed in this "Risk factors" section and many others, including:

- recalls or adverse developments or publicity;
- results of our preclinical studies and clinical studies, and the results of trials of our competitors or those of other companies in our market sector;
- our ability to enroll subjects in our future clinical trials;
- regulatory approval of HIL-214 or any other vaccine candidates, or limitations to specific label indications or target populations for its use, or changes or delays in the regulatory review process;
- regulatory or legal developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems;

- the success or failure of our efforts to develop, acquire or license additional vaccine candidates;
- innovations, clinical trial results, product approvals and other developments by our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our stock by insiders and stockholders, including Takeda;
- general economic, industry and market conditions, including inflation and increases and decreases in interest rates and financial institution instability, many of which are beyond our control;
- announcement of geopolitical events (including in relation to the conflict between Russia and Ukraine);
- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- changes in accounting standards, policies, guidelines, interpretations or principles.

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

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to significantly influence all matters submitted to stockholders for approval.

As of March 1, 2024, our executive officers, directors and greater than 5% stockholders, in the aggregate, own a majority of our outstanding common stock. As a result, such persons, acting together, have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

If we were to "reprice" any stock option or stock appreciation right without the approval of our stockholders, proxy advisory firms may issue a negative recommendation on certain of our compensation-related proposals at future annual meetings of our stockholders.

Our 2022 Incentive Award Plan permits the plan administrator, without the approval of our stockholders, to amend any outstanding stock option or stock appreciation right to reduce its price per share, other than in the context of corporate transactions or equity restructurings, as further described in such plan. Proxy advisory firms generally disfavor repricings without stockholder approval under their voting guidelines as currently in effect. In the event we choose to undertake a repricing in the future without the approval of our stockholders, proxy advisory firms may view such an action as a problematic practice under their voting policies and may issue adverse voting recommendations on certain compensation-

related proposals at future annual meetings of our stockholders. Certain institutional and other stockholders may similarly view such actions as problematic.

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

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

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

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

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

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of our IPO . However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer”, as defined under the Exchange Act, our annual gross revenue exceeds $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, unless the U.S. Securities and Exchange Commission (SEC) determines the new rules are necessary for protecting the public;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently

completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Provisions in our governing documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, our amended and restated certificate of incorporation provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will

be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees and result in increased costs for investors to bring a claim. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

General risk factors

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting and "pay versus performance" disclosure requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies have increased and may continue to increase our legal and financial compliance costs and to make some activities more time consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We could face criminal liability and other serious consequences for violations, which could harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls and anti-corruption and anti-money laundering laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of

export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed as a result of military conflicts in other countries may impact our ability to continue activities at future clinical trial sites within regions covered by such sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. These export and import controls and economic sanctions could also adversely affect our supply chain.

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, blizzards and other extreme weather conditions, fires, public health pandemics or epidemics (including, for example, the COVID-19 pandemic) and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers to produce HIL-214. Our ability to obtain clinical supplies of HIL-214 or any other vaccine candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters is located in Boston, Massachusetts, where we are subject to both severe winter and summer weather conditions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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

We and any of our third-party manufacturers or suppliers and current or potential future collaborators will use biological materials, potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

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

Unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, inflationary pressure and interest rate changes, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflicts between Russia and Ukraine and Israel and Hamas, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. More recently, the closures of Silicon Valley Bank and Signature Bank and their placement into receivership with the Federal Deposit Insurance Corporation

(FDIC) created bank-specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at SVB and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

Our ability to use net operating loss carryforwards and other tax attributes may be limited in connection with our IPO or other ownership changes.

We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income (subject to limitations), if any, until such unused losses expire (if at all). As of December 31, 2023, we had net operating loss (NOL) carryforwards of $47.8 million for federal income tax purposes and $36.5 million for state income tax purposes. Our state NOL carryforwards begin to expire in various amounts in 2041. Our federal NOL carryforwards will not expire but may generally only be used to offset 80% of taxable income, which may require us to pay federal income taxes in future years despite generating federal NOL carryforwards in prior years.

In addition, our NOL carryforwards and other tax attributes are subject to review and possible adjustment by the U.S. Internal Revenue Service (IRS) and state tax authorities. Furthermore, in general, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the Code), our federal NOL carryforwards may be or become subject to an annual limitation in the event we have had or have in the future an “ownership change.” For these purposes, an “ownership change” generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company’s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. We have not yet determined the amount of the cumulative change in our ownership resulting from our IPO or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. However, we believe that our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including potential changes in connection with our IPO. If we earn taxable income, such limitations could result in increased future income tax liability to us and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Changes in tax law may materially adversely affect our financial condition, results of operations and cash flows.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance. The likelihood of these changes being enacted or implemented is unclear. We are currently unable to predict whether such changes will occur. If such changes are enacted or implemented, we are currently unable to predict the ultimate impact on our business. We urge our investors to consult with their legal and tax advisors with respect to any changes in tax law and the potential tax consequences of investing in our common stock.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If one or more of the analysts who covers us downgrades our stock, or if we fail to meet the expectations of one or more of these analysts, our stock price would likely decline. If

one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2023. When we lose our status as an "emerging growth company" and do not otherwise qualify as a "smaller reporting company" with less than $100 million in annual revenue, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us, because biotechnology and biopharmaceutical companies

have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of our management's attention and resources, which could harm our business.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity Risk Management and Strategy

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program includes a cybersecurity incident response plan.

We design and assess our program based on the Center for Internet Security Framework (CISF). This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the CISF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise information technology environment;
- an external security team principally responsible for managing (i) our cybersecurity risk assessment processes, (ii) our security controls, and (iii) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- cybersecurity awareness training of our employees, incident response personnel, and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for service providers.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. We face risks from cybersecurity threats that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. See "Risk Factors – Risks Related to Our Business Operations and Industry - Our information technology systems, or those of any of our service providers, may fail or suffer security breaches, loss or leakage of data and other disruptions, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business."

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee (Audit Committee) oversight of cybersecurity and other information technology risks. The Audit Committee oversees management's implementation of our cybersecurity risk management program.

The Audit Committee receives periodic reports from management on our cybersecurity risks. In addition, management updates the Audit Committee, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential.

The Audit Committee reports to the full Board regarding its activities, including those related to cybersecurity. The full Board also receives briefings from management on our cyber risk management program. Board members receive presentations on cybersecurity topics from management, internal security staff or external experts as part of the Board's continuing education on topics that impact public companies.

Our management team, including the General Counsel and Chief Administrative Officer and Senior Director, IT, is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises our retained external cybersecurity consultants.

Our management team's experience includes extensive experience working in the information technology field and securing corporate information technology systems, including engaging with third party security vendors to perform cyber risk assessments and penetration testing.

Our management team supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the information technology environment.

Item 2. Properties

We lease space for our principal offices and laboratory in Boston, Massachusetts pursuant to a written lease for approximately 32,000 square feet. The current term of our lease expires in December 2032. We believe that our existing facilities will be sufficient for our needs for the foreseeable future.

Item 3. Legal Proceedings

We are not currently subject to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common stock is traded on the Nasdaq Global Select Market under the symbol “HLVX.”

Holders of Common Stock

As of March 1, 2024, there were 49,695,646 shares of common stock issued and held by approximately 30 stockholders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Securities Authorized for Issuance Under Equity Compensation Plans

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

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Unregistered Sales of Equity Securities

During the year ended December 31, 2023, we did not issue any securities which were unregistered under the Securities Act and required to be disclosed herein.

Use of Proceeds

On April 28, 2022, our registration statement on Form S-1 (File No. 333-264159) was declared effective by the SEC for our IPO. At the closing of the offering on May 3, 2022, we sold 13,529,750 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,764,750 additional shares, at an initial public offering price of $17.00 per share and received gross proceeds of $230.0 million, which resulted in net proceeds to us of approximately $209.5 million, after deducting underwriting discounts and commissions of approximately $16.1 million and offering-related transaction costs of approximately $4.4 million. None of the expenses associated with the initial public offering were paid to directors, officers, persons owning ten percent or more of any class of equity securities, or to their associates, or to our affiliates. J.P. Morgan Securities LLC, SVB Securities LLC, Stifel, Nicolaus & Company, Incorporated and Guggenheim Securities, LLC acted as joint book-running managers for the offering.

There has been no material change in the planned use of proceeds from our IPO from that described in the Prospectus dated April 28, 2022 filed pursuant to Rule 424(b) under the Securities Act with the SEC on April 29, 2022. As of December 31, 2023, we estimate that we have used approximately $148.4 million of the proceeds from our IPO for general corporate purposes, including to fund the clinical development of HIL-214.

Issuer Repurchases of Equity Securities.

None.

Item 6. [Reserved]

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

You should read the following discussion and analysis together with our consolidated financial statements and related notes included in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. For a complete discussion of forward-looking statements, see the section above entitled "Forward Looking Statements." 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 under the caption "Item 1A. Risk Factors."

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines. Our initial program, HIL-214, is a virus-like particle (VLP) based vaccine candidate for the prevention of moderate-to-severe acute gastroenteritis (AGE) caused by norovirus infection. It is estimated that norovirus causes nearly 700 million cases of illness and more than 200,000 deaths worldwide per year, as well as significant additional economic and social burden. To date, HIL-214 has been studied in nine clinical trials conducted by Takeda and LigoCyte, which collectively generated safety data from more than 4,500 subjects and immunogenicity data from more than 2,200 subjects, including safety and immunogenicity data from more than 800 pediatric subjects. A randomized, placebo-controlled Phase 2b field efficacy trial enrolled 4,712 adult subjects, and HIL-214 was well tolerated and demonstrated clinical proof of concept in preventing moderate-to-severe cases of AGE from norovirus infection. In September 2021, an open investigational new drug (IND) application was transferred to us from Takeda, under which we initiated a Phase 2b clinical trial, NEST-IN1 (Norovirus Efficacy and Safety Trial in Infants, or NOR-212), in May 2022 to evaluate the safety, immunogenicity, and efficacy of HIL-214 in infants. In May 2022, we completed enrollment of the prespecified 200 subject run-in for NEST-IN1. We resumed enrollment in NEST-IN1 in August 2022, following the prespecified safety assessment by the clinical trial's data monitoring committee. In December 2022, we reported positive interim immunogenicity results for the first 200 subjects of NEST-IN1. We expect to report top-line safety and clinical efficacy data in mid-2024. Based on the results from NEST-IN1, if positive, we plan to proceed to a pivotal Phase 3 efficacy trial in infants. We expect that the Phase 3 trial will enroll approximately 7,000 to 12,000 subjects that will be randomized 1:1 into the vaccine or control arm. We believe HIL-214 has the potential to be the first ever vaccine approved for norovirus-related illness and will help grow HilleVax into a leading global vaccines company.

We commenced our operations in 2019 and have devoted substantially all of our resources to date to organizing and staffing our company, business planning, raising capital, in-licensing intellectual property related to our initial vaccine candidate, HIL-214, preparing for and managing our clinical trials of HIL-214, and providing other general and administrative support for our operations. We have funded operations to date primarily through the issuance of convertible promissory notes, commercial bank debt, the sale of common stock in our initial public offering (IPO) which closed in May 2022 and the sale of common stock in our underwritten public offering which closed in September 2023. As of December 31, 2023, we had cash, cash equivalents and marketable securities of $303.5 million. From inception to December 31, 2023, we raised aggregate gross proceeds of $137.2 million from the issuance of convertible promissory notes, we completed our IPO in May 2022, whereby we sold 13,529,750 shares of common stock at a public offering price of $17.00 per share, for net proceeds of approximately $209.5 million, after deducting underwriting discounts, commissions and offering costs of approximately $20.5 million, we borrowed $25.0 million in commercial bank debt and we completed an underwritten public offering in September 2023, whereby we sold 9,200,000 shares of our common stock, which included the exercise in full by the underwriters of their option to purchase 1,200,000 shares, at a public offering price of $12.50 per share, for total net proceeds of approximately $107.8 million.

We do not have any products approved for sale, have not generated any revenue and have incurred net losses since our inception. Our net losses for the years ended December 31, 2023 and 2022 were $123.6 million and $159.8 million, respectively. As of December 31, 2023, we had an accumulated deficit of $388.6 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical development activities, other research and development activities and pre-commercialization activities. We expect our expenses and operating losses will increase substantially as we advance HIL-214 through clinical trials, seek regulatory approval for HIL-214, expand our clinical, regulatory, quality, manufacturing and commercialization capabilities, incur significant commercialization expenses for marketing, sales, manufacturing and distribution in anticipation of obtaining potential marketing approval for HIL-214, obtain, maintain, protect and enforce our intellectual property, expand our general and administrative support functions, including hiring additional personnel.

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to meet our anticipated cash requirements through at least the next 12 months. We have never generated any revenue and do not expect to generate any revenue from product sales unless and until we successfully complete

development of, and obtain regulatory approval for, HIL-214, which will not be for several years, if ever. Accordingly, until such time as we can generate significant revenue from sales of HIL-214, if ever, we expect to finance our cash needs through equity offerings, our existing Loan Agreement, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market vaccine candidates that we would otherwise prefer to develop and market ourselves.

Financial Operations Overview

Our financial statements include the accounts of HilleVax (formerly MokshaCo, Inc. and also the receiving entity), North Bridge V, Inc. (North Bridge V) and YamadaCo III, Inc. (YamadaCo III), prior to being merged into a single entity effective February 8, 2021. Our financial statements also include the accounts of our wholly-owned subsidiary HilleVax GmbH subsequent to its formation in May 2021 and our wholly-owned subsidiary HilleVax Security Corporation subsequent to its formation in December 2021. The functional currency of our Company, HilleVax GmbH and HilleVax Security Corporation is the U.S. dollar. HilleVax, North Bridge V and YamadaCo III were entities under common control of Frazier Life Sciences X, L.P. or its affiliates (Frazier), as a result of, among other things, Frazier's: (i) ownership of a majority of the outstanding capital stock of each of the companies; (ii) financing of each of the companies; (iii) control of board of directors of each of the companies; and (iv) management of each of the companies. All of the companies were formed for the purpose of identifying potential assets around which to form an operating company. As the merged entities were under common control, the financial statements report the financial position, results of operations and cash flows of the merged companies for all periods presented. All intercompany transactions have been eliminated in consolidation.

License Agreement with Takeda

On July 2, 2021, we and Takeda Vaccines, Inc. (Takeda), a subsidiary of Takeda Pharmaceutical Company Limited, entered into a license agreement (the Takeda License), pursuant to which we exclusively in-licensed certain intellectual property rights to commercialize HIL-214 products worldwide (excluding Japan) (the Territory). We will be responsible, at our cost, for the development, manufacture and commercialization of HIL-214 products. We are obligated to use commercially reasonable efforts to develop and commercialize HIL-214 products in the Territory, and to seek regulatory approval for such products throughout the world.

We paid Takeda upfront consideration consisting of 840,500 shares of our common stock and a warrant to purchase 5,883,500 shares of our common stock (the Takeda Warrant). We further agreed that, in the event that Takeda's fully-diluted ownership, including the Takeda Warrant, represents less than a certain specified percentage of our fully-diluted capitalization, including shares issuable upon conversion of outstanding convertible promissory notes, calculated immediately prior to the closing of our IPO, we would issue an additional warrant to purchase shares of common stock such that Takeda would hold a certain specified percentage of the fully-diluted capitalization immediately before the closing of our IPO (the Takeda Warrant Right). The Takeda Warrant was fully exercised in November 2022. The Takeda Warrant Right expired in connection with our IPO and no additional warrant was issued. We also paid Takeda $2.5 million in cash upon the consummation of our convertible note financing in August 2021 and paid Takeda $2.5 million in March 2022 upon release of certain drug products and completion of certain regulatory activities. We are required to make to Takeda a one-time payment of $7.5 million upon achievement of a specified development milestone and commercial milestone payments of up to $150.0 million in the aggregate if certain annual sales targets for HIL-214 products are met in the Territory. We agreed to pay Takeda tiered high-single digit to low-teen percentage royalties on net sales of HIL-214 products in the Territory, subject to specified offsets and reductions, and Takeda agreed to pay us tiered mid-single digit to low-double digit percentage royalties on net sales of HIL-214 products in Japan, subject to specified offsets and reductions. Royalties will be payable, on a product-by-product and country-by-country basis beginning on the first commercial sale of such product in such country, until the later of (i) the expiration of the licensed patents covering the applicable product, (ii) the expiration of regulatory exclusivity in such country, or (iii) 20 years following the first commercial sale of such product in such country.

Transitional Services Agreement with Takeda

As contemplated by the Takeda License, on December 17, 2021, we and Takeda entered into a Transitional Services Agreement (the TSA). Pursuant to the TSA, Takeda has agreed to provide, on a transitional basis following the effective date of the Takeda License, certain services related to research and development and regulatory assistance services, oversight and management of ongoing clinical and research studies, and maintenance of certain third-party vendor

contracts. In consideration for the services provided under the TSA, we have agreed to pay certain specified amounts to Takeda in cash for such services and certain pass-through costs. For the years ended December 31, 2023 and 2022, we incurred $0.4 million and $2.4 million, respectively, of research and development expenses for Takeda's services.

License Agreement with Kangh

On January 8, 2024, we entered into an exclusive license agreement with Chengdu Kanghua Biological Products Co., Ltd. (Kangh), for rights to Kangh's hexavalent VLP vaccine candidate for norovirus (the Kangh License), which we refer to as HIL-216, outside of Greater China. In consideration of the Kangh License, we will pay an upfront amount of $15.0 million with the potential for additional payments of up to $255.5 million upon achieving certain development and sales milestones. Kangh is also eligible to receive a single-digit tiered royalty on net sales outside of Greater China.

Components of Results of Operations

Operating Expenses

Research and Development

During 2023 and 2022, our research and development expenses have primarily been related to the development of HIL-214. Research and development expenses are recognized as incurred, and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Research and development expenses include:

- salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in research and development efforts;
- external research and development expenses incurred under agreements with CROs and consultants to conduct and support our planned clinical trials of HIL-214; and
- costs related to manufacturing HIL-214 for our planned clinical trials.

We plan to substantially increase our research and development expenses for the foreseeable future as we continue the development of HIL-214 and begin clinical development of HIL-216. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of HIL-214, HIL-216 or any other vaccine candidates due to the inherently unpredictable nature of clinical and preclinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast whether HIL-214 or any other vaccine candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

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

- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects;
- the number of subjects that participate in the trials;
- the number of doses evaluated in the trials;
- the costs and timing of manufacturing HIL-214 and placebo for use in our trials;
- the drop-out or discontinuation rates of clinical trial subjects;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the phase of development of the vaccine candidate;

- the impact of any interruptions to our operations or to those of the third parties with whom we work due to any future pandemic or other disease outbreaks or geopolitical events or war; and
- the safety, purity, potency, immunogenicity and efficacy of the vaccine candidate.

In-Process Research and Development

In-process research and development expenses for the year ended December 31, 2022 relate to the Takeda License, and include an aggregate $2.5 million contingent payment upon the release of certain drug products and the completion of certain regulatory activities, which have no alternative future use. We did not incur any in-process research and development expenses during the year ended December 31, 2023.

General and Administrative

General and administrative expenses consist of salaries and employee-related costs for personnel in executive, finance and other administrative functions, legal fees relating to intellectual property and corporate matters, and professional fees for accounting, auditing and consulting services. We anticipate that our general and administrative expenses will increase substantially in the future to support our research and development activities, pre-commercial preparation activities for HIL-214 and, if any vaccine candidate receives marketing approval, commercialization activities. We also anticipate increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs associated with operating as a public company.

Interest Income

Interest income consists of interest earned on our cash, cash equivalents and marketable securities.

Interest Expense

Interest expense consists of interest on our then outstanding convertible promissory notes and our term loan facility.

Change in Fair Value of Warrant Liabilities

In connection with the Takeda License, we issued the Takeda Warrant and Takeda Warrant Right (together, the Takeda Warrants). The Takeda Warrants were accounted for as liabilities until they met all the conditions for equity classification due to (i) insufficient authorized shares for the Takeda Warrant and (ii) the Takeda Warrant Right is not indexed to our own stock. Prior to our IPO, we adjusted the carrying value of the Takeda Warrants to their estimated fair value at each reporting date, with any change in fair value of the warrant liabilities recorded as an increase or decrease to change in fair value of warrant liabilities in the consolidated statements of operations. The Takeda Warrant, which became exercisable upon our IPO, was for the purchase of 5,883,500 shares of our common stock at an exercise price of $0.0000595 per share and was fully exercised in November 2022. As a result of increasing our authorized shares of common stock in the second quarter of 2022, the Takeda Warrant met the requirements to be equity classified, and we reclassified the fair value of the Takeda Warrant to stockholders' equity. The Takeda Warrant Right expired upon the closing of our IPO without effect to the financial statements since no fair value was allocated to it at that time. Prior to the reclassification to stockholders' equity, the fair value of the Takeda Warrants was derived from the model used to estimate the fair value of our common stock and, upon reclassification, the fair value was based on our IPO price.

Change in Fair Value of Convertible Promissory Notes

We issued convertible promissory notes in 2019, 2020 and 2021 for which we elected the fair value option. We adjusted the carrying value of our convertible promissory notes to their estimated fair value at each reporting date, with any change in fair value of the convertible promissory notes recorded as an increase or decrease to change in fair value of convertible promissory notes in our consolidated statements of operations. All outstanding convertible promissory notes and related accrued interest converted into shares of our common stock immediately prior to the closing of our IPO.

Prior to our IPO, the fair value of our convertible promissory notes was estimated using a scenario-based analysis that estimated the fair value of the convertible promissory notes based on the probability-weighted present value of expected future investment returns, considering possible outcomes available to the noteholders, including various IPO, settlement, equity financing, corporate transactions and dissolution scenarios. The conversion date fair value of the convertible

promissory notes was reclassified to stockholders' equity using our publicly traded closing price on the date the convertible promissory notes were converted to common stock.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations for the periods indicated (in thousands):

	Year Ended December 31,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 106,683	$ 45,908	$ 60,775
In-process research and development	—	2,500	(2,500)
General and administrative	26,662	16,705	9,957
Total operating expenses	133,345	65,113	68,232
Loss from operations	(133,345)	(65,113)	(68,232)
Other income (expense):			
Interest income	$ 9,706	3,875	5,831
Interest expense	(2,392)	(3,414)	1,022
Change in fair value of convertible promissory notes	—	(51,469)	51,469
Change in fair value of warrant liabilities	—	(43,575)	43,575
Other income (expense)	2,465	(113)	2,578
Total other income (expense)	9,779	(94,696)	104,475
Net loss	$ (123,566)	$ (159,809)	$ 36,243

Research and development expenses. Research and development expenses were $106.7 million and $45.9 million for the years ended December 31, 2023 and 2022, respectively. The increase of $60.8 million primarily consisted of $43.3 million of clinical development expenses for HIL-214, largely driven by the commencement of the NEST-IN1 study in 2022, $13.6 million of personnel-related expenses, including $4.9 million of stock-based compensation expense, primarily due to increased headcount, $1.4 million of facility and related expenses, primarily related to our Boston operating lease which commenced in April 2022, $1.2 million of consulting expenses, and $1.3 million of other expenses.

In-process research and development expenses. We had $2.5 million of in-process research and development expenses for the year ended December 31, 2022 related to the Takeda License, which was entered into in 2021. We did not incur any in-process research and development expenses for the year ended December 31, 2023.

General and administrative expenses. General and administrative expenses were $26.7 million and $16.7 million for the years ended December 31, 2023 and 2022, respectively. The increase of $10.0 million primarily consisted of $7.3 million of personnel-related expenses, including $5.7 million of stock-based compensation expense, primarily due to increased headcount, $1.5 million of facility and related expenses, primarily related to our Boston operating lease which commenced in April 2022, and $1.1 million of other expenses.

Other income (expense). Other income of $9.8 million for the year ended December 31, 2023 primarily consisted of $9.7 million of interest income on our cash, cash equivalents and marketable securities and $2.5 million of other income primarily related to the accretion of discounts to maturity on our marketable securities, partially offset by $2.4 million of interest expense on our term loan facility. Other expense of $94.7 million for the year ended December 31, 2022 primarily consisted of $51.5 million of other expense related to the increase in fair value of our convertible promissory notes, $43.6 million of other expense related to the increase in fair value of the Takeda Warrant, $3.4 million of interest expense on our outstanding convertible promissory notes and term loan facility, offset by $3.9 million of interest income on our cash and cash equivalents.

Liquidity and Capital Resources

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future as we continue the development and potential commercialization of HIL-214, and may never become profitable. We have funded our operations to date primarily through the issuance of convertible promissory notes, the net proceeds raised from our IPO, an underwritten public offering in September 2023 and

borrowings under our term loan facility. As of December 31, 2023, we had cash, cash equivalents and marketable securities of $303.5 million.

Term Loan Facility

On April 18, 2022, we entered into a Loan and Security Agreement (the Existing Loan Agreement and, as amended by the First and Second Amendments (as defined below), the Loan Agreement) with Hercules Capital, Inc., as administrative and collateral agent (in such capacity, Hercules), and the lenders from time to time party thereto (the Lenders), providing for term loans (Term Loans) of up to $75.0 million. Prior to June 16, 2023, we had borrowed $15.0 million in term loans under the Existing Loan Agreement and had the right thereunder to borrow (i) an additional $15.0 million of term loans until June 30, 2023 (Term Loan Tranche 1), (ii) an additional $20.0 million of term loans until June 30, 2023 (Term Loan Tranche 2), and (iii) subject to the achievement of certain clinical development milestones by the Company, an additional $25.0 million until March 31, 2024 (Term Loan Tranche 3).

On June 16, 2023, we entered into a First Amendment to Loan and Security Agreement (the First Amendment) with Hercules and the Lenders party thereto, which amended the Existing Loan Agreement. In connection with the First Amendment, we borrowed $10.0 million under Term Loan Tranche 1. Additionally, the First Amendment, among other things, amended the following: (i) with respect to the remaining $5.0 million under Term Loan Tranche 1, modified the period during which the Company may borrow thereunder to start on December 1, 2023 and end May 31, 2024 (or such earlier date if Lenders elect in their sole discretion), (ii) with respect to Term Loan Tranche 2, modified the period during which we may borrow thereunder to start on December 1, 2023 and end May 31, 2024 (or such earlier date if Lenders elect in their sole discretion) and (iii) with respect to Term Loan Tranche 3, (a) added as a new condition to borrow thereunder that (x) our Phase 2b clinical trial evaluating the safety, immunogenicity and efficacy of HIL-214 in infants (NEST-IN1) has achieved the protocol-specified primary efficacy endpoint and (y) HIL-214 has demonstrated acceptable safety results in the NEST-IN1 clinical trial, and, as a result, we support the initiation of a Phase 3 registrational trial as the next immediate step in the development of HIL-214 (the Tranche 3 Milestone) and (b) modified the period during which we may borrow thereunder to start on the date we achieve the Tranche 3 Milestone and end on the earlier of (x) June 15, 2024 and (y) 30 days following the date we achieve the Tranche 3 Milestone.

On November 9, 2023, the Company entered into a Second Amendment to Loan and Security Agreement (the "Second Amendment") with Hercules and the Lenders party thereto, which amended the Existing Loan Agreement. The Second Amendment amended the following: (i) with respect to the remaining $5.0 million under Term Loan Tranche 1, modified the period during which the Company may borrow thereunder to start on January 1, 2024 and end July 19, 2024 (or such earlier date if Lenders elect in their sole discretion), (ii) with respect to Term Loan Tranche 2, modified the period during which the Company may borrow thereunder to start on January 1, 2024 and end July 19, 2024 (or such earlier date if Lenders elect in their sole discretion) and (iii) with respect to Term Loan Tranche 3, modified the period during which the Company may borrow thereunder to end on the earlier of (x) September 15, 2024 and (y) 30 days following the date the Company achieves the Tranche 3 Milestone. The Company did not incur any fees in connection with the Second Amendment. All Term Loans are subject to a minimum draw amount of $5.0 million and no event of default under the Loan Agreement having occurred and is continuing. The borrowings under the Loan Agreement are collateralized by substantially all of our assets, including intellectual property and certain other assets.

The Term Loans bear (a) cash interest at a floating rate of the higher of (i) the Wall Street Journal prime rate (or 5.00% if less) plus 1.05%, or (ii) 4.55% (interest rate of 6.05% as of December 31, 2023), and (b) additional interest (PIK Interest) at a per annum rate equal to 2.85%, with such interest being added to the outstanding principal balance of the Term Loans on a monthly basis. The monthly payments consist of interest-only through June 1, 2025 or, if prior to April 30, 2025, we achieve the Tranche 3 Milestone, subject to reasonable verification by Hercules, through June 1, 2026. Subsequent to the interest-only period, the Term Loans will be payable in equal monthly installments of principal, plus accrued and unpaid interest, through the maturity date of May 1, 2027. In addition, we are obligated to pay a final payment fee equal to the greater of (i) $2.145 million and (ii) 7.15% of the original principal amount of the Term Loans. We may elect to prepay all or a portion of the Term Loans prior to maturity, subject to a prepayment fee of up to 1.00% of the then outstanding principal balance and the pro rata application of such payment to the final payment fee. After repayment, no Term Loan amounts may be borrowed again.

The Loan Agreement contains certain customary affirmative and negative covenants and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding our operating accounts. The negative covenants include, among others, limitations on our ability to incur additional indebtedness and liens, merge with other companies or consummate certain changes of control, acquire other companies or businesses, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements, including the Takeda License, or enter into various specified transactions. Upon the occurrence of an event

of default, subject to any specified cure periods, all amounts owed by us would begin to bear interest at a rate that is 4.00% above the rate effective immediately before the event of default and may be declared immediately due and payable by Hercules, as collateral agent.

As of December 31, 2023, the total outstanding borrowings, including PIK interest, under the Loan Agreement were $25.6 million. As of December 31, 2023, future minimum principal, interest and final payment fees due under the Loan Agreement were approximately $34.0 million, with $1.6 million payable for the year ending December 31, 2023. See Note 9 to our consolidated financial statements included in Item 8 of this Annual Report.

Convertible Promissory Note Financings

From inception to July 2021, we issued an aggregate of $8.5 million of convertible promissory notes to Frazier (the Frazier Notes), bearing interest at per annum rates ranging from 0.12% to 2.52%. In August 2021, these notes and related accrued interest were exchanged for the August 2021 Notes described below.

On August 31, 2021, we entered into a note purchase agreement under which we issued $139.5 million of unsecured convertible promissory notes (the August 2021 Notes). Of the August 2021 Notes, $103.8 million were issued to new investors, $25.0 million were issued to Frazier for cash and $10.7 million were issued to Frazier in exchange for the then outstanding principal and accrued interest on the Frazier Notes. The August 2021 Notes bore interest at a rate of 6% per annum, compounded annually. The August 2021 Notes automatically converted into 10,672,138 shares of our common stock immediately prior to the completion of our IPO.

At-the-Market-Offering

On May 12, 2023, we entered into an At-the-Market Equity Offering Sales Agreement (Sales Agreement) with Stifel, Nicolaus & Company, Incorporated (the Agent), under which we may, from time to time at prevailing market prices, sell shares of our common stock having an aggregate offering price of up to $100.0 million in "at the market" offerings through the Agent. As of December 31, 2023, no sales have been made pursuant to the Sales Agreement.

Underwritten Public Offering

On September 22, 2023, we completed an underwritten public offering, whereby we sold 9,200,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,200,000 shares, at a public offering price of $12.50 per share for total net proceeds of $107.8 million.

Funding Requirements

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to meet our anticipated cash requirements through at least the next 12 months. In particular, we expect that our existing cash, cash equivalents and marketable securities will allow us to complete enrollment and dosing in, and report top-line safety and clinical efficacy data for, our Phase 2b NEST-IN1 study and technical transfer and manufacturing readiness for producing clinical trial supply for a Phase 3 study. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing vaccine candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

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

- the initiation, type, number, scope, results, costs and timing of, our planned clinical trials of HIL-214 and preclinical studies or clinical trials of HIL-216 or other potential vaccine candidates we may choose to pursue in the future, including any modifications to clinical development plans based on feedback that we may receive from regulatory authorities;
- the costs and timing of manufacturing for HIL-214 and placebo to be used in our planned clinical trials, as well as commercial scale manufacturing, if any vaccine candidate is approved;
- the costs, timing and outcome of regulatory meetings and reviews of HIL-214 or any other vaccine candidates;
- any delays and cost increases that may result from any future pandemic or other disease outbreak or geopolitical events or war;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;

- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional officers and clinical development and commercial personnel;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the timing and amount of the milestone, royalty or other payments we must make to Takeda and any future licensors;
- the costs and timing of establishing or securing sales and marketing capabilities if HIL-214 or other vaccine candidates are approved;
- our ability to receive recommendations from the ACIP or other foreign NITAGs, and achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- vaccine recipients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors; and
- costs associated with any products or technologies that we may in-license or acquire.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through equity offerings, the Loan Agreement, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, intellectual property, future revenue streams, research programs or vaccine candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our vaccine candidates even if we would otherwise prefer to develop and market such vaccine candidates ourselves.

Cash Flows

The following table sets forth a summary of the net cash flow activity for each of the periods indicated (in thousands):

	Year Ended December 31,	
	2023	2022
Net cash provided by (used in):		
Operating activities	$ (86,783)	$ (61,989)
Investing activities	(94,638)	(6,514)
Financing activities	118,698	224,969
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (62,723)	$ 156,466

Operating Activities

Net cash used in operating activities of $86.8 million for the year ended December 31, 2023 was primarily due to our net loss of $123.6 million, partially offset by a net change of $22.8 million in our operating assets and liabilities and $13.9 million of noncash charges, primarily related to $13.6 million of stock-based compensation costs. The net change in operating assets and liabilities was primarily due to a $14.4 million increase in accounts payable and accrued expenses in support of the growth in our operating activities, a $4.0 million increase prepaid expenses and other current assets and a $4.3 million increase in operating lease right-of-use assets and liabilities.

Net cash used in operating activities of $62.0 million for the year ended December 31, 2022 was primarily due to our net loss of $159.8 million and a net change of $4.3 million in our operating assets and liabilities, partially offset by $102.1 million of noncash charges primarily related to the $51.5 million change in fair value of the August 2021 Notes, the $43.6 million change in fair value of the Takeda Warrants, $1.1 million related to amortization of operating lease right-of-use assets, $2.5 million related to acquired in-process research and development, $3.0 million of stock-based compensation, $0.3 million related to amortization of debt discount and $0.1 million related to issuance of PIK interest debt. The net change in operating assets and liabilities was primarily due to an $11.1 million decrease in prepaid expenses and other current assets, offset by a $2.8 million increase in accounts payable and accrued expenses in support of the growth in our operating activities, a $2.9 million increase in accrued interest on our convertible promissory notes and $1.1 million related to operating lease right-of-use assets and liabilities.

Investing Activities

Net cash used in investing activities of $94.6 million for the year ended December 31, 2023 was primarily due to $143.8 million in purchases of marketable securities and $10.7 million of purchases of property and equipment, partially offset by $59.9 million in proceeds from sales or maturities of marketable securities.

Net cash used in investing activities of $6.5 million for the year ended December 31, 2022 was primarily due to $2.5 million of cash paid for purchased in-process research and development and $4.0 million of purchases of property and equipment.

Financing Activities

Net cash provided by financing activities of $118.7 million for the year ended December 31, 2023 was due to $107.8 million of net proceeds from the issuance of common stock in our underwritten public offering, $9.8 million of net proceeds from borrowings under our term loan facility, $0.5 million in proceeds from the issuance of stock under our stock purchase plan and $0.6 million in proceeds from the exercise of common stock options.

Net cash provided by financing activities of $225.0 million for the year ended December 31, 2022 was primarily due to $210.3 million of net proceeds from our IPO and $14.7 million of net proceeds from borrowings under our term loan facility.

Contractual Obligations and Commitments

In March 2022, we entered into an operating lease for office and laboratory space located in Boston, Massachusetts (as amended, the Boston Lease). The Boston Lease commenced in April 2022 with base rental payments beginning in January 2023. The Boston Lease includes certain tenant improvement allowances for the reimbursement of up to $6.3 million of costs incurred by us, and an option for us to extend the lease for a period of five years. Under the terms of the Boston Lease, we provided the lessor with an irrevocable standby letter of credit secured by restricted cash in the amount of $1.6 million. In addition, we have a minor operating lease for a facility in Switzerland. As of December 31, 2023, future minimum operating lease payments were approximately $36.0 million, with $3.6 million of payments for the year ending December 31, 2024. See Note 6 to our consolidated financial statements included in Item 8 of this Annual Report for additional information regarding this operating lease agreement.

As of December 31, 2023, the total outstanding borrowings, including PIK interest, under the Loan Agreement were $25.6 million. See Note 9 to our consolidated financial statements included in Item 8 of this Annual Report for additional information regarding the Loan Agreement.

Under the Takeda License, we have milestone payment obligations that are contingent upon the achievement of certain development milestones and specified levels of product sales and are required to make certain royalty payments in connection with the sale of products developed under the agreement. We are currently unable to estimate the timing or likelihood of achieving the milestones or making future product sales. In addition, we have payment obligations under the TSA. See above and Note 8 to our consolidated financial statements included in Item 8 of this Annual Report for additional information regarding the Takeda License and TSA.

Under the Kangh License, we have milestone payment obligations that are contingent upon the achievement of certain development and sales milestones. We may also be required to make a single-digit tiered royalty payments on net sales outside of Greater China. We are currently unable to estimate the timing or likelihood of achieving the milestones or making future product sales. See above and Note 8 to our consolidated financial statements included in Item 8 of this Annual Report for additional information regarding the Kangh License.

We enter into contracts in the normal course of business for contract research services, contract manufacturing services, professional services and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States (GAAP). The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements and accompanying notes. We evaluate these estimates and judgments 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.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included in Item 8 of this Annual Report, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Accrued research and development expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our 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. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development and contract manufacturing services 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. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In 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 accrual or prepaid expense accordingly. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

In-process research and development

We evaluate whether acquired intangible assets are a business under applicable accounting standards. Additionally, we evaluate whether the acquired assets have a future alternative use. Intangible assets that do not have future alternative use, such as the Takeda License, are considered acquired in-process research and development. When the acquired in-process research and development assets are not part of a business combination, the value of the consideration paid is expensed on the acquisition date.

Fair value of warrant liabilities and convertible promissory notes

As described above, prior to our IPO, our warrant liabilities and convertible promissory notes were revalued at each reporting period with changes in the fair value of the liabilities recorded as a component of other income (expense) in the

consolidated statements of operations. See Note 2 to our consolidated financial statements included in Item 8 of this Annual Report for information concerning certain of the specific assumptions we used in determining the fair value of our warrant liabilities and convertible promissory notes. There are significant judgments and estimates inherent in the determination of the fair value of these liabilities. If we had made different assumptions including, among others, those related to the timing and probability of various corporate scenarios, discount rates, volatilities and exit valuations, the carrying values of our warrant liabilities and convertible promissory notes, and our net loss and net loss per common share could have been significantly different.

Stock-based compensation expense

Stock-based compensation expense represents the cost of the grant date fair value of equity awards, primarily consisting of stock options and employee stock purchase rights, recognized on a straight-line basis over the requisite service period for stock options and over the respective offering period for employee stock purchase plan rights, with forfeitures recognized as they occur. Since all equity awards from inception to July 1, 2021 were issued prior to us obtaining the Takeda License on July 2, 2021, we have not recognized any material amount of stock-based compensation and do not have any material amounts of unrecognized stock-based compensation related to those awards.

We estimate the fair value of option grants using the Black-Scholes option pricing model. Estimating the fair value of equity awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of variables, including the risk-free interest rate, the expected stock price volatility, the expected term of stock options, the expected dividend yield and the fair value of the underlying common stock on the date of grant. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop. See Note 10 to our consolidated financial statements included elsewhere in this Annual Report for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted during 2023 and 2022.

JOBS Act and Smaller Reporting Company

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the JOBS Act), we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of our IPO, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements included in Item 8 of this Annual Report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable to a smaller reporting company.

Item 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of HilleVax, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of HilleVax, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) 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.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2021.

San Diego, California
March 20, 2024

HilleVax, Inc.
Consolidated Balance Sheets
(in thousands, except share and par value data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 216,678	$ 279,401
Marketable securities	86,805	—
Prepaid expenses and other current assets	7,195	11,212
Total current assets	310,678	290,613
Property and equipment, net	14,018	5,586
Operating lease right-of-use assets	18,082	19,359
Restricted cash	1,631	1,631
Other assets	25	22
Total assets	$ 344,434	$ 317,211
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable (includes related party amounts of $0 and $141, respectively)	$ 7,461	$ 4,744
Accrued expenses (includes related party amounts of $33 and $140, respectively)	18,553	8,210
Accrued interest	134	55
Current portion of operating lease liability	3,118	37
Total current liabilities	29,266	13,046
Operating lease liability, net of current portion	22,831	21,569
Long-term debt, net of debt discount	25,244	14,792
Other long-term liabilities	1,568	575
Total liabilities	78,909	49,982
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; authorized shares— 50,000,000 at December 31, 2023 and December 31, 2022; no shares issued and outstanding at December 31, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; authorized shares— 500,000,000 at December 31, 2023 and December 31, 2022; issued shares—48,497,853 and 39,240,746 at December 31, 2023 and December 31, 2022, respectively; outstanding shares—47,666,438 and 37,656,037 at December 31, 2023 and December 31, 2022, respectively	5	4
Additional paid-in capital	654,986	532,499
Accumulated other comprehensive loss	(907)	(281)
Accumulated deficit	(388,559)	(264,993)
Total stockholders' equity	265,525	267,229
Total liabilities and stockholders' equity	$ 344,434	$ 317,211

See accompanying notes.

HilleVax, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31,	
	2023	2022
Operating expenses:		
Research and development (includes related party amounts of $362 and $2,426, respectively)	$ 106,683	$ 45,908
In-process research and development - related party	—	2,500
General and administrative (includes related party amounts of $0 and $40, respectively)	26,662	16,705
Total operating expenses	133,345	65,113
Loss from operations	(133,345)	(65,113)
Other income (expense):		
Interest income	9,706	3,875
Interest expense (includes related party amounts of $0 and $717, respectively)	(2,392)	(3,414)
Change in fair value of convertible promissory notes (includes related party amounts of $0 and $13,196, respectively)	—	(51,469)
Change in fair value of warrant liabilities - related party	—	(43,575)
Other income (expense)	2,465	(113)
Total other income (expense)	9,779	(94,696)
Net loss	$ (123,566)	$ (159,809)
Other comprehensive loss:		
Unrealized loss on marketable securities	(6)	—
Pension and other postemployment benefits	(620)	(281)
Total comprehensive loss	$ (124,192)	$ (160,090)
Net loss per share, basic and diluted	$ (3.04)	$ (5.89)
Weighted-average shares of common stock outstanding, basic and diluted	40,598,482	27,147,314

See accompanying notes.

HilleVax, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
(in thousands, except share data)

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2021	6,599,886	$ 1	$ 4,426	$ —	$ (105,184)	$ (100,757)
Issuance of common stock in connection with initial public offering, net of issuance costs of $20,491	13,529,750	1	209,514	—	—	209,515
Conversion of August 2021 Notes and accrued interest into common shares	10,672,138	1	215,363	—	—	215,364
Conversion of Takeda Warrant liability into equity	—	—	100,020	—	—	100,020
Exercise of Takeda Warrant	5,883,500	1	—	—	—	1
Vesting of restricted shares	958,777	—	—	—	—	—
Stock—based compensation	—	—	3,003	—	—	3,003
Issuance of common stock under share-based compensation arrangements	11,986	—	173	—	—	173
Pension and other postemployment benefits	—	—	—	(281)	—	(281)
Net loss	—	—	—	—	(159,809)	(159,809)
Balance at December 31, 2022	37,656,037	4	532,499	(281)	(264,993)	267,229
Vesting of restricted shares	683,410	—	—	—	—	—
Stock—based compensation	—	—	13,590	—	—	13,590
Issuance of common stock under share-based compensation arrangements	126,991	—	1,108	—	—	1,108
Issuance of common stock in connection with underwritten public offering, net	9,200,000	1	107,789	—	—	107,790
Unrealized loss on marketable securities	—	—	—	(6)	—	(6)
Pension and other postemployment benefits	—	—	—	(620)	—	(620)
Net loss	—	—	—	—	(123,566)	(123,566)
Balance at December 31, 2023	47,666,438	$ 5	$ 654,986	$ (907)	$ (388,559)	$ 265,525

See accompanying notes.

HilleVax, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities		
Net loss	$ (123,566)	$ (159,809)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	879	1
Stock-based compensation	13,590	3,003
Change in fair value of convertible promissory notes (includes related party amounts of $0 and $13,196, respectively)	—	51,469
Change in fair value of warrant liabilities - related party	—	43,575
Amortization of operating lease right-of-use assets	1,277	1,147
Amortization of debt discount	567	292
Issuance of PIK interest debt	548	87
Acquired in-process research and development - related party	—	2,500
Net accretion/amortization of premiums and discounts on marketable securities	(2,921)	—
Loss on disposal of property and equipment	—	42
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	4,017	(11,071)
Accounts payable, accrued expenses and other long-term liabilities (includes related party amounts of $(248) and $(4,652), respectively)	14,404	2,819
Accrued interest (includes related party amounts of $0 and ($717), respectively)	79	2,852
Operating lease right-of-use assets and liabilities	4,343	1,104
Net cash used in operating activities	(86,783)	(61,989)
Cash flows from investing activities		
Cash paid for purchased in-process research and development	—	(2,500)
Purchases of property and equipment	(10,748)	(4,014)
Purchases of marketable securities	(143,790)	—
Proceeds from sales or maturities of marketable securities	59,900	—
Net cash used in investing activities	(94,638)	(6,514)
Cash flows from financing activities		
Proceeds from issuance of common stock under share-based compensation arrangements	1,108	—
Proceeds from issuance of common stock in initial public offering	—	230,006
Payment of initial public offering costs	—	(19,702)
Proceeds from issuance of common stock in underwritten public offering, net of issuance costs	107,790	—
Proceeds from issuance of long-term debt, net of issuance costs	9,800	14,665
Net cash provided by financing activities	118,698	224,969
Net increase (decrease) in cash, cash equivalents and restricted cash	(62,723)	156,466
Cash, cash equivalents and restricted cash—beginning of period	281,032	124,566
Cash, cash equivalents and restricted cash—end of period	$ 218,309	$ 281,032
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 1,392	$ 193
Supplemental disclosure of noncash investing and financing activities		
Operating lease	$ —	$ 20,317
Unpaid property and equipment purchases	$ 136	$ 1,573
Conversion of convertible promissory notes and interest into common stock	$ —	$ 215,364
Conversion of warrant liability into equity	$ —	$ 100,020
Accreted final interest payment fees	$ 463	$ 252
Settlement of ESPP liability in common stock	$ —	$ 173

See accompanying notes.

1. Organization

Organization

HilleVax, Inc. (the “Company” or “HilleVax”) was incorporated in the state of Delaware in March 2020 under the name MokshaCo, Inc. (“MokshaCo”). On February 8, 2021, MokshaCo changed its name to HilleVax and merged with North Bridge V, Inc. (“North Bridge V”) and YamadaCo III, Inc. (“YamadaCo III”), each a Delaware corporation formed in 2019, with HilleVax being the surviving entity (the “Merger”). The Company is a biopharmaceutical company focused on developing and commercializing novel vaccines.

Forward Stock Split

On April 22, 2022, the Company effected a 1.681-for-1 forward split of shares of the Company’s common stock (the “Forward Stock Split”). The par value of the common stock was not adjusted as a result of the Forward Stock Split and the authorized shares were increased to 50,000,000 shares of common stock in connection with the Forward Stock Split. The accompanying financial statements and notes to the financial statements give retroactive effect to the Forward Stock Split for all periods presented, unless otherwise indicated.

Liquidity and Capital Resources

From inception to December 31, 2023, the Company has devoted substantially all of its efforts to organizing and staffing the Company, business planning, raising capital, in-licensing its initial vaccine candidate, HIL-214, preparing for and managing its clinical trials of HIL-214, and providing other general and administrative support for these operations. The Company has a limited operating history, has never generated any revenue, and the sales and income potential of its business is unproven. The Company has incurred net losses and negative cash flows from operating activities since its inception and expects to continue to incur net losses into the foreseeable future as it continues the development and potential commercialization of HIL-214. From inception to December 31, 2023, the Company has funded its operations through the issuance of convertible promissory notes, commercial bank debt, the sale of 13,529,750 shares of common stock for net proceeds of approximately $209.5 million in its initial public offering ("IPO") which closed in May 2022, and the sale of 9,200,000 shares of common stock for net proceeds of approximately $107.8 million in its underwritten public offering which closed in September 2023 (see Note 10).

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. Management is required to perform a two-step analysis over the Company’s ability to continue as a going concern. Management must first evaluate whether there are conditions and events that raise substantial doubt about the Company’s ability to continue as a going concern (Step 1). If management concludes that substantial doubt is raised, management is also required to consider whether its plans alleviate that doubt (Step 2). Management believes that it has sufficient working capital on hand to fund operations through at least the next twelve months from the date these financial statements were issued. There can be no assurance that the Company will be successful in acquiring additional funding, if needed, that the Company’s projections of its future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's financial statements include the accounts of HilleVax Security Corporation, a wholly-owned subsidiary formed in Massachusetts, and HilleVax GmbH, a wholly-owned subsidiary formed in Zurich, Switzerland. The functional currency of the Company, HilleVax Security Corporation and HilleVax GmbH is the U.S. dollar. The Company’s assets and liabilities that are not denominated in the functional currency are remeasured into U.S. dollars at foreign currency exchange rates in effect at the balance sheet date except for nonmonetary assets, which are remeasured at historical foreign currency exchange rates in effect at the date of transaction. Net realized and unrealized gains and losses from foreign currency transactions and remeasurement are reported in other income (expense), in the consolidated statements of operations and were not material for the periods presented. All intercompany transactions have been eliminated in consolidation.

Use of Estimates

The Company's consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of the Company's consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements relate to accruals for research and development expenses, and prior to the Company's IPO, the valuation of convertible promissory notes, warrant liabilities and various other equity instruments. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results could differ materially from those estimates and assumptions.

Fair Value Option

As permitted under Accounting Standards Codification ("ASC") 825, *Financial Instruments*, ("ASC 825"), the Company has elected the fair value option to account for its convertible promissory notes issued through May 2022, when the convertible promissory notes converted into equity in connection with the Company's IPO. In accordance with ASC 825, the Company recorded these convertible promissory notes at fair value with changes in fair value recorded in the consolidated statements of operations. As a result of applying the fair value option, direct costs and fees related to the convertible promissory notes were recognized in the statement of operations as incurred and not deferred.

Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or non-recurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less when purchased to be cash equivalents. Cash and cash equivalents include cash in readily available checking accounts and money market funds.

Restricted Cash

Restricted cash consists of a money market account securing a standby letter of credit issued in connection with the Company's Boston Lease (as defined and described in Note 6).

Marketable Securities

Marketable securities represent holdings of available-for-sale marketable debt securities in accordance with the Company's investment policy. The Company has classified its investments with maturities beyond one year as current, based on their highly liquid nature and because such marketable securities represent the investment of cash that is available for current operations. Investments in marketable securities are recorded at fair value, with any unrealized gains and losses reported within accumulated other comprehensive income (loss) as a separate component of stockholders' equity (deficit) until realized, a determination is made that an other-than-temporary decline in market value has occurred or until the security has experienced a credit loss. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion, together with interest on securities

sold, is determined based on the specific identification method and any realized gains or losses on the sale of investments are reflected as a component of other income (expense).

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, marketable securities, and restricted cash. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Property and Equipment, Net

Property and equipment are stated at cost and depreciated on a straight-line basis over the estimated useful life of the related assets as follows:

	Estimated Useful Life
Computer equipment	3 years
Lab equipment	5 years
Furniture and fixtures	5 years
Leasehold improvements	3 – 10 years or term of lease

Repairs and maintenance costs are charged to expense as incurred.

Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. Lease terms are determined at the commencement date by considering whether renewal options and termination options are reasonably assured of exercise. For its long-term operating leases, the Company recognizes a lease liability and a right-of-use ("ROU") asset on its balance sheet and recognizes lease expense on a straight-line basis over the lease term. The lease liability is determined as the present value of future lease payments, reduced by any reimbursements for tenant improvements, using the discount rate implicit in the lease or, if the implicit rate is not readily determinable, an estimate of the Company's incremental borrowing rate. The ROU asset is based on the lease liability, adjusted for any prepaid or deferred rent, and reduced by any reimbursements for tenant improvements. The Company aggregates all lease and non-lease components for each class of underlying assets into a single lease component and variable charges for common area maintenance and other variable costs are recognized as expense as incurred. The Company has elected to not recognize a lease liability or ROU asset in connection with short-term operating leases and recognizes lease expense for short-term operating leases on a straight-line basis over the lease term. The Company does not have any financing leases.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, such as property and equipment, for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. Fair value would be assessed using discounted cash flows or other appropriate measures of fair value. The Company has not recognized any impairment losses through December 31, 2023.

Research and Development Expenses and Accruals

All research and development costs are expensed in the period incurred and consist primarily of salaries, payroll taxes, employee benefits, stock-based compensation charges for those individuals involved in research and development efforts, external research and development costs incurred under agreements with contract research organizations and consultants to conduct and support the Company's clinical trials of HIL-214.

The Company has entered into various research and development contracts with clinical research organizations, clinical manufacturing organizations and other companies. Payments for these activities are based on the terms of the individual

agreements, which may differ from the pattern of costs incurred, and payments made in advance of performance are reflected in the accompanying balance sheets as prepaid expenses. The Company records accruals for estimated costs incurred for ongoing research and development activities. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the prepaid or accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

In-Process Research and Development

The Company evaluates whether acquired intangible assets are a business under applicable accounting standards. Additionally, the Company evaluates whether the acquired assets have a future alternative use. Intangible assets that do not have future alternative use are considered acquired in-process research and development. When the acquired in-process research and development assets are not part of a business combination, the value of the consideration paid is expensed on the acquisition date.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expenses and expensed as incurred since recoverability of such expenditures is uncertain.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of equity awards, primarily consisting of stock options, restricted common stock, and employee stock purchase rights, recognized on a straight-line basis over the requisite service period for stock options and restricted common stock, and over the respective offering period for employee stock purchase plan rights. The Company recognizes forfeitures as they occur.

Benefit plans

The Company has established a defined contribution savings plan for its employees in the United States under Section 401(k) of the Internal Revenue Code, and a defined benefits plan for its employees outside of the United States.

The defined benefits plan is valued by an independent actuary using the projected unit credit method. The liabilities correspond to the projected benefit obligations of which the discounted net present value is calculated based on years of employment, expected salary increase, and pension adjustments. The Company reviews its actuarial assumptions on an annual basis and makes modifications to the assumptions based on current rates and trends. This plan is recognized under ASC 715, *Compensation - Retirement Benefits*.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the consolidated statements of operations in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (i) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense in the consolidated statements of operations. Any accrued interest and penalties are included within the related tax liability

in the consolidated balance sheets. The Company did not recognize any interest or penalties during the periods presented.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. For the years ended December 31, 2023 and December 31, 2022, comprehensive loss included losses on the Company's pension benefit obligation and unrealized losses on marketable securities.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business as one operating segment.

Net Loss Per Share

Basic net loss per share is computed by dividing the consolidated net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. The Company has excluded weighted-average unvested shares of 1,232,828 shares and 2,080,038 shares from the basic weighted-average number of common shares outstanding for the years ended December 31, 2023 and 2022, respectively. Diluted net loss per share is computed by dividing the consolidated net loss by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. Potentially dilutive common stock equivalents are comprised of unvested common stock, common stock options, and contingently issuable shares under the Company's employee stock purchase plan. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as inclusion of the potentially dilutive common stock equivalents would be antidilutive.

Potentially dilutive securities not included in the calculation of diluted net loss per share, because to do so would be anti-dilutive, are as follows (in common stock equivalent shares):

	December 31,	
	2023	2022
Common stock options	3,896,061	2,111,989
Unvested common stock	1,571,716	1,584,709
ESPP shares	8,473	4,420
Total potentially dilutive shares	5,476,250	3,701,118

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (“JOBS Act”). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected to avail itself of this exemption from new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recently Adopted Accounting Standards

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, Financial Instruments – Credit Losses (Topic 326), to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. To achieve this objective, the amendments in Topic 326 replace the incurred loss impairment methodology in current U.S. GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. We adopted Topic 326 on January 1, 2023. The adoption did not have a material impact on our consolidated financial statements’.

Recently Issued Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280)*. The amendments in this update expand segment disclosure requirements, including new segment disclosure requirements for entities with a single reportable segment among other disclosure requirements. This update is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740)*. The amendments in this update expand income tax disclosure requirements, including additional information pertaining to the rate reconciliation, income taxes paid, and other disclosures. This update is effective for annual periods beginning after December 15, 2024. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

3. Fair Value Measurements

The Company's cash, cash equivalents, marketable securities, and restricted cash are carried at fair value, determined according to the fair value hierarchy discussed in Note 2. The carrying values of the Company's prepaid expenses and other current assets, accounts payable, and accrued liabilities, approximate fair value due to their short maturities. The estimated fair value of the Company's long-term debt approximated the carrying amount given its floating interest rate basis. Warrant liabilities and convertible promissory notes were recorded at fair value on a recurring basis until they converted to equity in connection with the Company's IPO, which closed in May 2022.

The following tables present the Company's fair value hierarchy for its assets that are measured at fair value on a recurring basis and indicate the level within the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value (in thousands):

		Fair Value Measurements at December 31, 2023 Using:		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents				
Money market funds	$ 209,659	$ 209,659	$ —	$ —
Marketable securities:				
U.S. treasury notes	43,050	43,050	—	—
U.S government agency bonds	43,755	—	43,755	—
Total	$ 296,464	$ 252,709	$ 43,755	$ —

		Fair Value Measurements at December 31, 2022 Using:		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents				
Money market funds	$ 277,043	$ 277,043	$ —	$ —
Total	$ 277,043	$ 277,043	$ —	$ —

U.S. government money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. As of December 31, 2023, the Company's marketable securities consisted of U.S. Treasury notes which were valued based on Level 1 inputs and agency bonds which were valued based on Level 2 inputs. In determining the fair value of its agency bonds, the Company relied on quoted prices for similar securities in active markets or other inputs that are observable or can be corroborated by observable market data.

None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

4. Marketable Securities

As of December 31, 2023, the fair value of available-for-sale marketable debt securities by type of security was as follows (in thousands):

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities:				
U.S. treasury notes	$ 43,036	$ 16	$ (2)	$ 43,050
U.S. government agency bonds	43,775	4	(24)	43,755
Total	$ 86,811	$ 20	$ (26)	$ 86,805

At December 31, 2023, all available-for-sale marketable securities had contractual maturities of less than one year. The Company did not hold any marketable debt securities as of December 31, 2022.

As of December 31, 2023, the Company reviewed its investment portfolio to assess the unrealized losses on its available-for-sale investments. In making this assessment, the Company considered the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors. The Company also evaluated whether it intended to sell the security and whether it was more likely than not that the Company would be required to sell the security before recovering its amortized cost basis. The Company determined no portion of the unrealized losses relate to a credit loss. There have been no impairments of the Company's assets measured and carried at fair value during the year ended December 31, 2023.

5. Other Balance Sheet Details

Property and Equipment

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

	December 31,	
	2023	2022
Computer equipment	$ 103	$ -
Furniture and equipment	377	11
Leasehold improvements	11,964	378
Lab equipment	2,116	—
Construction in progress	338	5,198
Total property and equipment, at cost	14,898	5,587
Less accumulated depreciation	880	1
Property and equipment, net	$ 14,018	$ 5,586

Depreciation expense for the year ended December 31, 2023 was $0.9 million. Depreciation expense for the year ended December 31, 2022 was not material.

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2023	2022
Accrued external research and development costs	$ 12,665	$ 3,510
Accrued payroll and payroll-related costs	5,233	4,018
Accrued professional costs	498	307
Other	157	375
Total accrued expenses	$ 18,553	$ 8,210

Cash, Cash Equivalents and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents and restricted cash recorded within the accompanying consolidated balance sheets that sum to the amounts shown in the consolidated statements of cash flows (in thousands):

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 216,678	$ 279,401
Restricted cash	1,631	1,631
Total cash, cash equivalents and restricted cash	$ 218,309	$ 281,032

6. Leases

Operating Leases

In August 2021, the Company entered into a five-year noncancelable operating lease for a facility in Switzerland, which it determined was an operating lease at the inception of the lease contract. The lease commencement date occurred in September 2021 when the Company gained access to the facility. The Company is obligated to make monthly rental payments that periodically escalate during the lease term and is subject to additional charges for common area maintenance and other costs. The Company has an option to extend the lease for a period of five years which the Company is not reasonably certain to exercise.

In March 2022, the Company entered into a lease for office and laboratory space located in Boston, Massachusetts (as amended, the “Boston Lease”), which it determined was an operating lease at the inception of the lease contract. The Boston Lease commenced in April 2022 with base rental payments beginning in January 2023. The Boston Lease includes certain tenant improvement allowances for the reimbursement of up to $6.3 million of costs incurred by the Company, and an option for the Company to extend the lease for a period of five years, which the Company is not reasonably certain to exercise. The Company determined that it owns the leasehold improvements related to the Boston Lease and, as such, reflected the $6.3 million lease incentive as a reduction of the rental payments used to measure the operating lease liability, and, in turn, the operating lease right-of-use asset as of the lease commencement date in April 2022. Between the lease commencement date and December 31, 2023, the Company recorded increases of $6.0 million to the operating lease liability as and when such lease incentives were received from the landlord. Under the terms of the Boston Lease, the Company provided the lessor with an irrevocable standby letter of credit secured by restricted cash in the amount of $1.6 million.

The following table summarizes operating lease expense for the year ended December 31, 2023 (in thousands):

	Year Ended December 31, 2023	Year Ended December 31, 2022
Lease expense:		
Operating lease expense	$ 3,115	$ 2,351

The Company incurred an immaterial amount of expense related to short-term leases and variable lease costs during the years ended December 31, 2023 and December 31, 2022.

The following table summarizes the lease term and discount rate for operating leases:

	December 31, 2023	December 31, 2022
Other information:		
Weighted-average remaining lease term	9.00	9.96
Weighted-average discount rate	7.4%	7.4%

As there was not an implicit rate within the leases, management estimated the incremental borrowing rate based on the rate of interest the Company would have to pay to borrow a similar amount on a collateralized basis over a similar term as well as by using a set of peer companies' incremental borrowing rates.

The following table summarizes the cash paid for amounts included in the measurement of lease liabilities (in thousands):

	December 31, 2023
Cash paid for amounts included in the measurement of operating lease liabilities (operating cash flows)	$ 3,487

At December 31, 2023, the future minimum noncancelable operating lease payments were as follows (in thousands):

	December 31, 2023
Years ending December 31:	
2024	3,589
2025	3,692
2026	3,787
2027	3,860
2028	3,974
Thereafter	17,101
Total undiscounted operating lease payments	36,003
Present value adjustment	(9,703)
Tenant improvement reimbursements	(351)
Operating lease liability	25,949
Less current portion of operating lease liability	3,118
Operating lease liability, net of current portion	$ 22,831

7. Related Party Transactions

Frazier Life Sciences X, L.P. or its affiliates ("Frazier") is a principal stockholder of the Company and is represented on the Company’s board of directors. From January 8, 2019 (inception) to December 31, 2023, the Company and Frazier reimbursed each other for various goods and services, including personnel related expenses, travel, insurance, facilities and other various overhead and administrative expenses. As of December 31, 2022, the Company had outstanding amounts due to Frazier of $6,000 related to these shared operating expenses. For the year ended December 31, 2022, the Company incurred $40,000 of shared operating expenses. For the year ended December 31, 2023, the Company did not incur any shared operating expenses related to Frazier.

As described in Note 9, the Company borrowed amounts from Frazier in connection with various convertible note financings. For the year ended December 31, 2022, the Company recognized a $13.2 million change in fair value of convertible promissory notes in connection with convertible promissory notes issued to Frazier. For the year ended December 31, 2022, the Company recognized $0.7 million of interest expense in connection with convertible promissory notes issued to Frazier. The convertible promissory notes automatically converted into 10,672,138 shares of the Company's common stock immediately prior to the completion of the IPO.

In connection with the Takeda License (as defined and described in Note 8), Takeda became a related party stockholder with representation on the Company’s board of directors. The Company and Takeda are party to a TSA (as defined and described in Note 8) under which the Company is obligated to pay Takeda for certain services, including pass-through costs, related to research and development and regulatory assistance services, oversight and management of ongoing clinical and research studies, and maintenance of third-party vendor contracts. For the years ended December 31, 2023 and 2022, the Company incurred $0.4 million and $2.4 million, respectively, of research and development expenses for Takeda’s services. As of December 31, 2023 and 2022, the Company had $33,000 and $0.3 million, respectively, of accounts payable and accrued expenses due to Takeda. See Note 8 for further information regarding the Company’s related party transactions with Takeda.

8. Commitments and Contingencies

License Agreement

On July 2, 2021, the Company entered into a license agreement with Takeda pursuant to which it was granted an exclusive sublicensable, royalty-bearing license (the "Takeda License") to develop and commercialize HIL-214 pharmaceutical products for all human uses on a worldwide basis outside of Japan (the "Territory").

The Company will be responsible, at its own cost, for the development, manufacture and commercialization of HIL-214 products in the Territory, and the Company will integrate certain Japan development activities into its development activities at its own cost. The Company is obligated to use commercially reasonable efforts to develop and commercialize HIL-214 products in the Territory, and to seek regulatory approval for such products throughout the world.

In consideration of the Takeda License, the Company (i) paid Takeda $2.5 million in cash, (ii) issued Takeda 840,500 shares of its common stock at a fair value of $4.4 million, (iii) issued Takeda a warrant (the "Takeda Warrant") to purchase 5,883,500 shares of its common stock at an exercise price of $0.0000595 per share, which was fully exercised in November 2022, and (iv) issued Takeda a warrant right (the "Takeda Warrant Right") to receive an additional common stock warrant should Takeda's fully-diluted ownership of the Company, including the Takeda Warrant, represent less than a certain specified percentage of the fully-diluted capitalization, including shares issuable upon conversion of outstanding convertible promissory notes, calculated immediately prior to the earlier of the closing of the Company's IPO or a change of control transaction, at an initial fair value of $34,000. In addition, the Company is obligated to pay Takeda an aggregate of $2.5 million upon the release of certain drug product and the completion of certain regulatory activities, which payment was made in March 2022, $7.5 million upon the achievement of a specified development milestone, up to an aggregate of $150.0 million in sales milestones upon the achievement of specified annual sales levels of HIL-214 products in the Territory, and tiered high single-digit to low-teen percentage royalties on net sales of HIL-214 products in the Territory, subject to specified offsets and reductions. Takeda has agreed to pay the Company tiered mid-single digit to low-double digit percentage royalties on net sales of HIL-214 products in Japan, subject to specified offsets and reductions. Royalties will be payable, on a product-by-product and country-by-country basis from the first commercial sale of such product in such country, until the latest of expiration of the licensed patents covering the applicable product, expiration of regulatory exclusivity in such country, or 20 years following first commercial sale of such product in such country. The obligations related to contingent payments are recognized in the accompanying consolidated financial statements when the contingency is resolved and the consideration is paid or becomes payable. As of December 31, 2023, none of the remaining contingent payments were due or payable.

Absent early termination, the Takeda License expires on a country-by-country and product-by-product basis upon the expiration of the applicable royalty term with respect to each product in each country, as applicable, or in its entirety upon the expiration of the royalty term with respect to the last product commercialized in the last country. The Company may terminate the Takeda License upon six months' prior written notice. The Company and Takeda may terminate the Takeda License in the case of the other party's insolvency, or upon prior written notice within a specified time period for the other party's material uncured breach. Takeda may terminate the Takeda License if the Company challenges licensed patents, or assists any third-party in challenging such patents.

The acquisition of the Takeda License has been accounted for as an asset acquisition as substantially all of the fair value is concentrated in a group of similar assets. In March 2022, the Company paid Takeda an aggregate $2.5 million contingent payment upon the release of certain drug products and the completion of certain regulatory activities, which have no alternative future use, and was recorded as in-process research and development in the Company's consolidated statement of operations for the year ended December 31, 2022. The Company did not make any milestone payments to Takeda during the year ended December 31, 2023.

Transitional Services Agreement with Takeda

As contemplated by the Takeda License, on December 17, 2021, the Company entered into a Transitional Services Agreement ("TSA") with Takeda under which the Company will be obligated to pay Takeda for certain services, including pass-through costs, related to research and development and regulatory assistance services, oversight and management of ongoing clinical and research studies, and maintenance of third party vendor contracts. The TSA and related activities are considered related party transactions. Unless earlier terminated under its terms, the TSA will remain in effect until all transitional services are completed. The Company may terminate the provision of any or all services under the TSA upon certain written notice. The Company and Takeda may terminate the TSA in the case of the other party's insolvency, or upon prior written notice within a specified time period for the other party's material uncured breach. Takeda may terminate the TSA for non-payment and, in certain circumstances, upon a change of control of the Company.

Contingencies

In the event the Company becomes subject to claims or suits arising in the ordinary course of business, the Company would accrue a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

9. Convertible Promissory Notes and Long-Term Debt

Frazier Convertible Note Financings

During 2019, 2020 and 2021, the Company issued the Frazier Notes for an aggregate of $8.5 million bearing interest at per annum rates ranging from 0.12% to 2.52%. An aggregate of $0.9 million of the Frazier Notes were issued in April, May and September of 2019 (the “2019 Frazier Notes”), an aggregate of $1.3 million of the Frazier Notes were issued in March, August and October of 2020 (the “2020 Frazier Notes”) and an aggregate of $6.3 million of Frazier Notes were issued from April to July 2021 (the “2021 Frazier Notes”). The Frazier Notes were generally scheduled to mature 12 to 18 months from the date of issuance. The Company recorded changes in the fair value of the Frazier Notes in the consolidated statements of operations. The Frazier Notes were exchanged for convertible promissory notes newly issued in connection with the August 2021 convertible note financing described below.

August 2021 Convertible Note Financing

On August 31, 2021, the Company entered into a note purchase agreement under which it issued the August 2021 Notes for an aggregate of $139.52 million. Of the August 2021 Notes, $103.75 million were issued to new investors, $25.0 million were issued to Frazier for cash and $10.77 million were issued to Frazier in exchange for the then outstanding principal and accrued interest on the Frazier Notes. The August 2021 Notes carried interest at a rate of 6% per annum, compounded annually. The principal and accrued interest on the August 2021 Notes automatically converted into 10,672,138 shares of the Company's common stock immediately prior to the completion of the IPO. Of these shares, 2,736,234 were issued to Frazier.

For the year ended December 31, 2022, the Company recognized a $51.5 million change in fair value of convertible promissory notes and recognized $2.8 million of interest expense in connection with convertible promissory notes.

Long-Term Debt

The Company’s Term Loan consists of the following (in thousands):

	December 31, 2023
Long-term debt	$ 25,000
Accumulated PIK interest	635
Total principal (including PIK interest)	25,635
Unamortized debt discount	(391)
Long-term debt, net of debt discount	$ 25,244

On April 18, 2022, the Company entered into a Loan and Security Agreement (the "Existing Loan Agreement” and, as amended by the First Amendment (as defined below) the "Loan Agreement") with Hercules Capital, Inc., as administrative and collateral agent (in such capacity, "Hercules"), and the lenders from time to time party thereto (the "Lenders"), providing for term loans (“Term Loans”) of up to $75.0 million. Prior to June 16, 2023, the Company had borrowed $15.0 million in term loans under the Existing Loan Agreement and had the right thereunder to borrow (i) an additional $15.0 million of term loans until June 30, 2023 (“Term Loan Tranche 1”), (ii) an additional $20.0 million of term loans until June 30, 2023 (“Term Loan Tranche 2”), and (iii) subject to the achievement of certain clinical development milestones by the Company, an additional $25.0 million until March 31, 2024 (“Term Loan Tranche 3”).

On June 16, 2023, the Company entered into a First Amendment to Loan and Security Agreement (the "First Amendment") with Hercules and the Lenders party thereto, which amended the Existing Loan Agreement. In connection with the First Amendment, the Company borrowed $10.0 million under Term Loan Tranche 1. Additionally, the First Amendment, among other things, amended the following: (i) with respect to the remaining $5.0 million under Term Loan Tranche 1, modified the period during which the Company may borrow thereunder to start on December 1, 2023 and end May 31, 2024 (or such earlier date if Lenders elect in their sole discretion), (ii) with respect to Term Loan Tranche 2,

modified the period during which the Company may borrow thereunder to start on December 1, 2023 and end May 31, 2024 (or such earlier date if Lenders elect in their sole discretion) and (iii) with respect to Term Loan Tranche 3, (a) added as a new condition to borrow thereunder that (x) the Company's Phase 2b clinical trial evaluating the safety, immunogenicity and efficacy of HIL-214 in infants ("NEST-IN1") has achieved the protocol-specified primary efficacy endpoint and (y) HIL-214 has demonstrated acceptable safety results in the NEST-IN1 clinical trial, and, as a result, the Company supports the initiation of a Phase 3 registrational trial as the next immediate step in the development of HIL-214 (the "Tranche 3 Milestone") and (b) modified the period during which the Company may borrow thereunder to start on the date the Company achieves the Tranche 3 Milestone and end on the earlier of (x) June 15, 2024 and (y) 30 days following the date the Company achieves the Tranche 3 Milestone. The First Amendment was accounted for as a debt modification; as such, the financing costs of $0.2 million were reflected as additional debt discount and is amortized as an adjustment to interest expense over the term of the First Amendment.

On November 9, 2023, the Company entered into a Second Amendment to Loan and Security Agreement (the "Second Amendment") with Hercules and the Lenders party thereto, which amended the Existing Loan Agreement. The Second Amendment amended the following: (i) with respect to the remaining $5.0 million under Term Loan Tranche 1, modified the period during which the Company may borrow thereunder to start on January 1, 2024 and end July 19, 2024 (or such earlier date if Lenders elect in their sole discretion), (ii) with respect to Term Loan Tranche 2, modified the period during which the Company may borrow thereunder to start on January 1, 2024 and end July 19, 2024 (or such earlier date if Lenders elect in their sole discretion) and (iii) with respect to Term Loan Tranche 3, modified the period during which the Company may borrow thereunder to end on the earlier of (x) September 15, 2024 and (y) 30 days following the date the Company achieves the Tranche 3 Milestone. The Company did not incur any fees in connection with the Second Amendment. All Term Loans are subject to a minimum draw amount of $5.0 million and no event of default under the Loan Agreement having occurred and is continuing. The borrowings under the Loan Agreement are collateralized by substantially all of our assets, including intellectual property and certain other assets.

The Term Loans bear (a) cash interest at a floating rate of the higher of (i) the Wall Street Journal prime rate (or 5.00% if less) plus 1.05%, or (ii) 4.55% (interest rate of 6.05% as of December 31, 2023), and (b) additional interest ("PIK Interest") at a per annum rate equal to 2.85%, with such interest being added to the outstanding principal balance of the Term Loans on a monthly basis. The monthly payments consist of interest-only through June 1, 2025 or, if prior to April 30, 2025, the Company achieves the Tranche 3 Milestone, subject to reasonable verification by Hercules, through June 1, 2026. Subsequent to the interest-only period, the Term Loans will be payable in equal monthly installments of principal, plus accrued and unpaid interest, through the maturity date of May 1, 2027. In addition, the Company is obligated to pay a final payment fee equal to the greater of (i) $2.145 million and (ii) 7.15% of the original principal amount of the Term Loans (which is $2.1 million as of December 31, 2023). The final payment fee is recorded as a debt discount amortized over the life of the debt. The Company may elect to prepay all or a portion of the Term Loans prior to maturity, subject to a prepayment fee of up to 1.00% of the then outstanding principal balance and the pro rata application of such payment to the final payment fee. After repayment, no Term Loan amounts may be borrowed again.

The Loan Agreement contains certain customary affirmative and negative covenants and events of default. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding its operating accounts. The negative covenants include, among others, limitations on the Company's ability to incur additional indebtedness and liens, merge with other companies or consummate certain changes of control, acquire other companies or businesses, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements, including the Takeda License, or enter into various specified transactions. Upon the occurrence of an event of default, subject to any specified cure periods, all amounts owed by the Company would begin to bear interest at a rate that is 4.00% above the rate effective immediately before the event of default and may be declared immediately due and payable by Hercules, as collateral agent.

As of December 31, 2023, the Company had borrowed $25.0 million pursuant to the Loan Agreement. During the year ended December 31, 2023, the Company recognized interest expense of $2.4 million related to the Term Loans using the effective interest method. Included in such expense was $0.5 million, related to accretion of the final payment fee to other long-term liabilities, $0.5 million of PIK interest, $1.3 million of coupon interest, and an immaterial amount of debt discount amortization.

Future minimum principal and interest payments, including the final payment fee, as of December 31, 2023 are as follows (in thousands):

	December 31, 2023
Years ending December 31:	
2024	$ 1,599
2025	8,433
2026	13,303
2027	10,645
Total principal payments, interest payments and final payment fee	33,980
Less: interest, PIK interest and final payment fee	(8,345)
Long-term debt	$ 25,635

10. Stockholders' Equity

Initial Public Offering

On May 3, 2022, the Company completed its IPO whereby it sold 13,529,750 shares of common stock at a public offering price of $17.00 per share, for net proceeds of approximately $209.5 million, after deducting underwriting discounts, commissions and offering costs of approximately $20.5 million. In connection with the Company's IPO, the Company increased the number of authorized shares of the Company's common stock and preferred stock to 500,000,000 shares and 50,000,000 shares, respectively.

At-the-Market-Offering

On May 12, 2023, the Company entered into an At-the-Market Equity Offering Sales Agreement (the "Sales Agreement") with Stifel, Nicolaus & Company, Incorporated (the "Agent"), pursuant to which the Company may offer and sell shares of the Company's common stock having an aggregate offering price of up to $100.0 million from time to time, in "at the market" offerings through the Agent. Sales of the shares of common stock, if any, will be made at prevailing market prices at the time of sale, or as otherwise agreed with the Agent. The Agent will receive a commission from the Company of up to 3.0% of the gross proceeds of any shares of common stock sold under the Sales Agreement. The Company is not obligated to sell, and the Agent is not obligated to buy or sell, any shares of common stock under the Sales Agreement. As of December 31, 2023, no sales have been made pursuant to the Sales Agreement.

Underwritten Public Offering

On September 22, 2023, the Company completed an underwritten public offering whereby it sold 9,200,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,200,000 shares, at a public offering price of $12.50 per share for total net proceeds of approximately $107.8 million, after underwriting discounts and commissions and estimated offering costs.

2021 Equity Incentive Plan

On February 8, 2021, the Company's board of directors and stockholders approved and adopted the HilleVax, Inc. 2021 Equity Incentive Plan (the "2021 Plan"). The term of the 2021 Plan is ten years from the adoption date. Under the 2021 Plan, the Company may grant stock options, restricted stock, restricted stock units, and other stock-based awards to employees, directors or consultants of the Company and its subsidiaries. The stock options granted under the plan generally vest over a four-year period from the vesting commencement date. Upon the effectiveness of the 2022 Plan defined and described below, no further grants will be made under the 2021 Plan, and any outstanding awards granted under the 2021 Plan will remain subject to the terms of the 2021 Plan and applicable award agreements.

2022 Incentive Award Plan

In April 2022, the Company's board of directors and stockholders approved the 2022 Incentive Award Plan (the "2022 Plan," and together with the 2021 Plan, the "Plans") under which the Company may grant stock options, restricted stock, dividend equivalents, restricted stock units, stock appreciation rights, and other stock or cash-based awards to its employees, consultants and directors. The 2022 Plan became effective in connection with the Company's IPO and will remain in effect until the tenth anniversary of its effective date, which will be April 28, 2032, unless earlier terminated by

the Company's board of directors. The number of shares of the Company's common stock initially available for issuance under awards granted pursuant to the 2022 Plan was the sum of (1) 4,900,000 shares of the Company's common stock, plus (2) 216,849 shares remaining available for issuance under the 2021 Plan as of the effective date of the 2022 Plan, plus (3) any shares subject to outstanding awards under the 2021 Plan as of the effective date of the 2022 Plan that become available for issuance under the 2022 Plan thereafter in accordance with its terms. The number of shares initially available for issuance will be increased by an annual increase on January 1 of each calendar year ending in and including 2032, equal to the lesser of (1) 5% of the shares of common stock outstanding on the final day of the immediately preceding calendar year and (2) such smaller number of shares as determined by the Company's board of directors. As of December 31, 2023, 7,197,502 shares were reserved for issuance under the 2022 Plan, of which 3,576,043 shares remained available for future issuance.

2022 Employee Stock Purchase Plan

In April 2022, the Company's board of directors and stockholders approved the 2022 Employee Stock Purchase Plan (the "2022 ESPP"). The 2022 ESPP became effective in connection with the Company's IPO. The 2022 ESPP permits eligible employees who elect to participate in an offering under the ESPP to have up to a specified percentage of their eligible earnings withheld, subject to certain limitations, to purchase shares of common stock pursuant to the 2022 ESPP. The price of common stock purchased under the 2022 ESPP is equal to 85% of the lower of the fair market value of the common stock on the first trading day of the offering period or the relevant purchase date. A total of 410,000 shares of the Company's common stock was initially reserved for issuance under the 2022 ESPP. In addition, the number of shares available for issuance under the 2022 ESPP will be annually increased on January 1 of each calendar year ending in and including 2032, by an amount equal to the lesser of (1) 1% of the shares outstanding on the final day of the immediately preceding calendar year and (2) such smaller number of shares as is determined by the Company's board of directors, provided that no more than 10,000,000 shares of the Company's common stock may be issued under the 2022 ESPP.

A summary of the Company's stock option activity under the Plans is as follows (in thousands, except share and per share data):

	Number of Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance at December 31, 2022	2,111,989	$ 10.62	9.33	$ 13,330
Granted	2,035,225	16.88		
Exercised	(84,554)	7.27		
Cancelled	(166,599)	11.98		
Balance at December 31, 2023	3,896,061	$ 13.89	8.82	$ 11,826
Vested and expected to vest at December 31, 2023	3,896,061	$ 13.89	8.82	$ 11,826
Exercisable at December 31, 2023	884,268	$ 10.35	8.32	$ 5,219

Stock-Based Compensation Expense

The fair value of common stock is based on the closing price as reported on the date of grant on the primary stock exchange on which the Company's common stock is traded. The assumptions used in the Black-Scholes option pricing model to determine the fair value of stock option grants were as follows:

	Year Ended December 31,	
	2023	2022
Risk-free interest rate	3.5%–4.9%	1.9%–4.2%
Expected volatility	91.7%–95.9%	83.4%–94.3%
Expected term (in years)	5.5–6.1	5.3–6.1
Expected dividend yield	0%	0%

Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities similar to the expected term of the awards.

Expected volatility. Given the Company's limited historical stock price volatility data, the expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Expected term. The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historical exercise behavior, it determines the expected life assumption using the simplified method, for employees, which is an average of the contractual term of the option and its vesting period.

Expected dividend yield. The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends and, therefore, used an expected dividend yield of zero.

Stock-based compensation expense has been reported in the consolidated statements of operations as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Research and development	$ 6,582	$ 1,720
General and administrative	7,008	1,283
Total	$ 13,590	$ 3,003

The weighted average grant date fair value per share of option grants for the years ended December 31, 2023 and 2022 was $13.03 and $4.88, respectively. As of December 31, 2023, total unrecognized stock-based compensation cost related to stock options was approximately $28.9 million, which is expected to be recognized over a remaining weighted-average period of approximately 2.7 years.

A summary of the Company’s unvested shares is as follows:

	Number of Unvested Shares	Weighted Average Grant-Date Fair Value
Balance at December 31, 2022	1,584,709	$ 0.001
Shares granted	759,266	18.000
Shares forfeited	(88,849)	0.001
Share vested	(683,410)	0.001
Balance at December 31, 2023	1,571,716	—

The Company issued shares of restricted common stock during the year ended December 31, 2023, which consisted only of restricted stock units. The Company did not issue any shares of restricted common stock during the year ended December 31, 2022. The weighted average grant date fair value per share of restricted common stock grants for the year ended December 31, 2023 was $18.00. As of December 31, 2023, total unrecognized stock-based compensation cost related to restricted stock was approximately $10.3 million, which is expected to be recognized over a remaining weighted-average period of approximately 3.1 years. For accounting purposes, unvested shares of restricted common stock are not considered outstanding until they vest. As of December 31, 2023 and 2022, the Company had no material repurchase liability related to the unvested shares in the table above.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following:

	December 31, 2023
Common stock options outstanding	3,896,061
Shares available for issuance under the Plans	3,576,043
Shares available for issuance under the ESPP	732,137
	8,204,241

11. Pension and Other Postretirement Benefit Plans

401(k) Plan

The Company established a defined-contribution plan under Section 401(k) of the Internal Revenue Code (the 401(k) Plan). The 401(k) Plan covers all eligible employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Beginning November 2022, the Company made matching contributions equal to 100% of the employee's contributions, subject to a maximum of 4% of eligible compensation. The Company made matching contributions of $0.6 million during the year ended December 31, 2023. The matching contributions for the year ended December 31, 2022 were not material.

Pension Plan

The Company sponsors a defined benefit pension plan covering eligible employees in Switzerland. Under the defined benefit pension plan, the Company and certain of its employees with annual earnings in excess of government determined amounts are required to make contributions into a fund managed by an independent investment fiduciary. Employer contributions must be in an amount at least equal to the employee's contribution. Under U.S. GAAP, the Company is required to recognize the overfunded or underfunded status of a defined benefit pension and other postretirement plan as an asset or liability in its consolidated balance sheets and to recognize changes in that funded status in the year in which the changes occur through the changes in the pension and other postemployment benefits line on the consolidated statements of operations and comprehensive loss. The Company is also required to measure the funded status of a plan as of the date of its fiscal year-end for which consolidated financial statements are presented.

The following table sets forth the projected benefit obligation, fair value of plan assets, and the funded status of the Company's plan as of December 31, 2023 and 2022 (in thousands):

	December 31,	
	2023	2022
Change in benefit obligation		
Benefit obligation at beginning of year	$ 2,051	$ 1,017
Prior service cost	47	—
Service cost	246	120
Interest cost	60	6
Contributions paid by plan participants	169	92
Benefits deposited	1,692	692
Actuarial loss	598	114
Exchange rate adjustments	393	10
Benefit obligation at end of year	5,256	2,051
Fair value of plan assets at end of year	4,414	1,739
Funded status - deficit	$ (842)	$ (312)

The accumulated benefit obligation as of December 31, 2023 and 2022 was $5.1 million and $2.0 million respectively.

The components of net periodic benefit cost recognized in operating expense in the consolidated statements of operations and comprehensive loss and other amounts recognized in adjustment to pension liability in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2023 and 2022 were as follows (in thousands):

	December 31,	
	2023	2022
Service cost	$ 246	$ 120
Interest cost	60	6
Expected return on plan assets	(72)	(33)
Amortization of net loss	7	—
Total recognized in operating expense	241	93
Adjustment to pension liability	620	281
Total recognized other comprehensive loss	620	281
Total costs recognized in consolidated comprehensive loss	$ 861	$ 374

The weighted average actuarial assumptions used to determine net periodic benefit cost for the years ended December 31, 2023 and 2022 were as follows:

	December 31,	
	2023	2022
Discount rate	1.5%	1.9%
Inflation rate	1.0%	1.0%
Expected rate of return on plan assets	3.0%	2.5%
Rate of compensation increase	1.0%	1.0%

The demographic assumptions, including mortality and disability rates, used to determine the net periodic benefit costs for the years ended December 31, 2023 and 2022 were based on the LPP/BVG 2020 tables.

As of December 31, 2023, the pension plan benefits expected to be paid over the next ten years are as follows (in thousands):

	December 31, 2023
Years ending December 31:	
2024	$ 5
2025	10
2026	14
2027	19
2028	24
2029-2033	200
Total expected benefits to be paid	$ 272

The Company made contributions to the pension plan of approximately $0.4 million and $0.2 million during the year ended December 31, 2023 and 2022, respectively. The Company anticipates making contributions at similar levels during the next fiscal year.

12. Income Taxes

A reconciliation between the provision for income taxes and income taxes computed using the U.S. federal statutory corporate tax rate is as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Tax computed at federal statutory rate	$ (25,927)	$ (33,588)
State income taxes	(1,291)	(1,366)
Change in fair value of warrant liabilities	—	9,249
Convertible debt	—	11,396
Permanent differences and other	997	(354)
Research and development credits	(2,838)	—
Effect of rate change on deferred tax assets and liabilities	1,455	—
Change in valuation allowance	27,604	14,734
Other	—	(71)
Provision for income taxes	$ —	$ —

Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Intangible assets	$ 7,315	$ 8,406
Net operating loss carryforwards	10,323	6,950
Start up and organization costs	596	685
Capitalized research cost	27,564	9,337
Lease liability	5,654	4,979
Share based compensation	2,166	—
Tax credit carryforwards	3,577	—
Other, net	1,236	1,030
Total deferred tax assets	58,431	31,387
Valuation allowance	(54,491)	(26,930)
Deferred tax assets, net of allowance	$ 3,940	$ 4,457
Deferred tax liabilities:		
Right-of-use asset	$ (3,940)	$ (4,457)
Total deferred tax liabilities	(3,940)	(4,457)
Net deferred tax assets	$ —	$ —

The Company has established a valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets. The Company periodically evaluates the recoverability of the deferred tax assets. At such time as it is determined that it is more likely than not that deferred tax assets are realizable, the valuation allowance will be reduced. The Company has recorded a full valuation allowance of $54.5 million as of December 31, 2023 as it cannot conclude that it is more likely than not that the deferred tax assets will be realized primarily due to the generation of pre-tax book losses from its inception.

As of December 31, 2023, the Company has federal and state net operating loss carryforwards of approximately $47.8 million and $36.5 million, respectively. As a result of the Tax Cuts and Jobs Act of 2017, for U.S. federal income tax purposes, net operating losses generated after December 31, 2017 can be carried forward indefinitely, but are limited to 80% utilization against future taxable income each year. The state net operating loss carryforwards begin to expire in 2041.

Pursuant to Internal Revenue Code Sections 382 and 383, annual use of the Company's net operating loss may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an ownership change analysis pursuant to IRS Section 382. If ownership changes have occurred or occur in the future, the amount of remaining tax attribute carryforwards available to offset taxable income and income tax expense in future years may be restricted or eliminated. If eliminated, the related asset would be removed from deferred tax assets with a corresponding reduction in the valuation allowance.

The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While the Company believes that it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcome of examinations by tax authorities in determining the adequacy of its provision for income taxes.

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

	Year Ended December 31,	
	2023	2022
Beginning Balance	$ —	$ —
Increases (decreases) related to prior year tax positions	177	—
Increases related to current year tax positions	782	—
Ending Balance	$ 959	$ —

As of December 31, 2023, the Company has gross unrecognized tax benefits of $959,000, none of which would affect the effective tax rate due to a full valuation allowance. The Company does not anticipate any significant changes in its unrecognized tax benefits over the next twelve months. The Company's policy is to recognize the interest expense and/or

penalties related to income tax matters as a component of income tax expense. The Company has no accrual for interest or penalties on its balance sheet at December 31, 2023, and has not recognized interest and/or penalties in its statement of operations for the year ended December 31, 2023.

The Company is subject to taxation in the United States, Switzerland, and various states. The Company is not currently under examination by any taxing authorities. Due to the carryover of tax attributes, the statute of limitations is currently open for tax years since inception.

The Company's policy is to recognize interest and penalties related to income tax matters as a component of income tax expense. The Company has not recognized interest or penalties in its consolidated statements of operations since inception.

13. Subsequent Events

License Agreement

On January 8, 2024, the Company entered into an exclusive license agreement with Chengdu Kanghua Biological Products Co., Ltd. ("Kangh"), for rights to Kangh's hexavalent virus-like particle vaccine candidate for norovirus (the "Kangh License"), referred to by the Company as HIL-216, outside of Greater China. In consideration of the Kangh License, the Company will pay an upfront amount of $15.0 million with the potential for additional payments of up to $255.5 million upon achieving certain development and sales milestones. Kangh is also eligible to receive a single-digit tiered royalty on net sales outside of Greater China.

At-the-Market-Offering

The Company sold 1,016,950 shares of its common stock under its Sales Agreement for its at-the-market offering program subsequent to December 31, 2023 through March 20, 2024 for aggregate gross cash proceeds of $15.0 million, before deducting commission fees and offering expenses payable by the Company.

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

As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. The term "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Internal control over financial reporting is a process designed 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 and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management of the Company has assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2023. In making its assessment of internal control over financial reporting, management used the criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2023.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to an exemption provided by the JOBS Act for "emerging growth companies," and our status as a non-accelerated filer under the Exchange Act.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2023 that have materially affected, or are reasonably likely to

materially affect, our internal control over financial reporting.

Item 9B. Other Information

Rule 10b5-1 Trading Arrangements

On October 12, 2023, Aditya Kohli, Director and former Chief Operating Officer, adopted a rule 10b5-1 trading arrangement that is intended to satisfy the affirmative defense of Rule 10b5-1(c) for the sale of up to 108,000 shares of our common stock until May 22, 2024.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Except to the extent provided below, the information required by this Item 10 will be included in our Proxy Statement to be filed with the SEC and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions. A current copy of the Code of Business Conduct and Ethics is available on the Corporate Governance section of our website at www.hillevax.com. If we make any substantive amendments to the Code of Business Conduct and Ethics or grants any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the 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 11 will be included in our Proxy Statement to be filed with the SEC and is incorporated herein by reference.

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

The information required by this Item 12 will be included in our Proxy Statement to be filed with the SEC and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our Proxy Statement to be filed with the SEC and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 will be included in our Proxy Statement to be filed with the SEC and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this Annual Report on Form 10-K:

(1) Financial Statements

The financial statements of HilleVax, Inc., together with the report thereon of Ernst & Young LLP, an independent registered public accounting firm, are included in Item 8 of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

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

(3) Exhibits

The exhibits required by Item 601 of Regulation and Item 15(b) of this Annual Report are listed in the Exhibit Index immediately preceding the signature page of this Annual Report. The exhibits listed in the Exhibit Index are incorporated by reference herein.

Item 16. Form 10-K Summary

None.

Exhibit Index

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation of HilleVax, Inc.	8-K	5/3/22	3.1	
3.2	Amended and Restated Bylaws of HilleVax, Inc.	8-K	12/8/23	3.1	
4.1	Specimen stock certificate evidencing the shares of common stock	S-1	4/6/22	4.1	
4.2	Warrant to purchase shares of common stock issued to Takeda Vaccines, Inc., dated July 2, 2021	S-1	4/6/22	4.2	
4.3	Note Purchase Agreement, dated August 31, 2021, by and among the Registrant and the other parties party thereto	S-1	4/6/22	4.3	
4.4	Description of Registered Securities	10-K	3/17/23	4.4	
10.1#	HilleVax, Inc. 2021 Equity Incentive Plan, as amended, including form of stock option agreement and form of restricted stock grant notice and restricted stock agreement thereunder	S-1	4/6/22	10.1	
10.2#	HilleVax, Inc. 2022 Incentive Award Plan and form of stock option agreement and form of restricted stock unit agreement thereunder	S-1/A	4/25/22	10.2	
10.3#	HilleVax, Inc. 2022 Employee Stock Purchase Plan	S-1/A	4/25/22	10.3	
10.4#	Non-Employee Director Compensation Program	10-Q	8/14/23	10.3	
10.5#	Form of Indemnification Agreement for Directors and Officers	S-1	4/6/22	10.9	
10.6#	Amended and Restated Employment Letter Agreement, dated January 6, 2023, by and between Robert Hershberg and the Registrant	10-K	3/17/23	10.6	
10.7#	Third Amended and Restated Employment Letter Agreement, dated as of February 19, 2024, by and between Aditya Kohli and the Registrant				X
10.8#	Second Amended and Restated Employment Letter Agreement, dated as of January 6, 2023, by and between David Socks and the Registrant	10-K	3/17/23	10.8	
10.9#	Amended and Restated Employment Letter Agreement, dated as of January 6, 2023, by and between Shane Maltbie and the Registrant	10-K	3/17/23	10.9	
10.10#	Employment Letter Agreement, dated as of January 6, 2023, by and between Astrid Borkowski and the Registrant	10-K	3/17/23	10.10	
10.11#	Employment Letter Agreement, dated as of January 16, 2024, by and between Sean McLoughlin				X
10.12†	License Agreement, dated July 2, 2021, by and between Takeda Vaccines, Inc. and the Registrant	S-1	4/6/22	10.10	
10.13†	Transitional Services Agreement, dated December 17, 2021, by and between Takeda Vaccines, Inc. and the Registrant	S-1	4/6/22	10.11	
10.14†	Loan and Security Agreement, dated April 18, 2022, by and among the Registrant and Hercules Capital, Inc.	S-1/A	4/18/22	10.12	
10.15	First Amendment to Loan and Security Agreement, dated June 16, 2023, by and between the Registrant and Hercules Capital, Inc.	10-Q	8/14/23	10.2	
10.16	Second Amendment to Loan and Security Agreement, dated November 9, 2023, by and between the Company and Hercules Capital, Inc.	10-Q	11/9/23	10.1	
10.17	At-the-Market Equity Offering Sales Agreement, dated May 12, 2023, by and between the Registrant and Stifel, Nicolaus & Company, Incorporated	S-3	5/12/23	1.2	
21.1	List of Subsidiaries of the Registrant				X
23.1	Consent of Independent Registered Public Accounting Firm				X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X

31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
97	Policy Relating to Recovery of Erroneously Awarded Compensation	X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document With Embedded Linkbase Documents	X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	X

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* This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

\# Indicates management contract or compensatory plan.

† Portions of this exhibit have been omitted in compliance with Regulation S-K Item(b)(10)(iv).

^ Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the SEC.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

HilleVax, Inc.

Date: March 20, 2024

By: /s/ Robert Hershberg, M.D., Ph.D.
Robert Hershberg, M.D., Ph.D.
Chairman, President and Chief Executive Officer

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

Name	Title	Date
/s/ Robert Hershberg, M.D., Ph.D. Robert Hershberg, M.D., Ph.D.	Chairman, President and Chief Executive Officer *(Principal Executive Officer)*	March 20, 2024
/s/ Shane Maltbie Shane Maltbie	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 20, 2024
/s/ Shelley Chu, M.D., Ph.D. Shelley Chu, M.D., Ph.D.	Director	March 20, 2024
/s/ Nanette Cocero, Ph.D. Nanette Cocero, Ph.D.	Director	March 20, 2024
/s/ Gary Dubin, M.D. Gary Dubin, M.D.	Director	March 20, 2024
/s/ Julie Gerberding, M.D., M.P.H. Julie Gerberding, M.D., M.P.H.	Director	March 20, 2024
/s/ Patrick Heron Patrick Heron	Director	March 20, 2024
/s/ Jeryl Hilleman Jeryl Hilleman	Director	March 20, 2024
/s/ Aditya Kohli, Ph.D. Aditya Kohli, Ph.D.	Director	March 20, 2024
/s/ Jaime Sepulveda, M.D., D.Sc., M.P.H. Jaime Sepulveda, M.D., D.Sc., M.P.H.	Director	March 20, 2024

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