

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**HILLEVAX, INC.**

(Exact name of registrant as specified in its charter)

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

**2836**  
(Primary Standard Industrial  
Classification Code Number)

**85-0545060**  
(I.R.S. Employer  
Identification No.)

**75 State Street, Suite 100 - #9995  
Boston, Massachusetts 02109  
(617) 213-5054**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Rob Hershberg, M.D., Ph.D.**  
**Chairman, President and Chief Executive Officer**  
**HilleVax, Inc.**

**75 State Street, Suite 100 - #9995  
Boston, Massachusetts 02109  
(617) 213-5054**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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 7(a)(2)(B) of the Securities Act.

**CALCULATION OF REGISTRATION FEE**

Title of Each Class of Securities To Be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)
Common Stock, \$0.0001 par value per share	\$	\$

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes shares of common stock that the underwriters have the option to purchase.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED \_\_\_\_\_, 2022

## Preliminary Prospectus

# shares



## Common stock

\_\_\_\_\_

This is the initial public offering of shares of common stock by HilleVax, Inc. We are selling \_\_\_\_\_ shares of our common stock. The initial public offering price is expected to be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share.

Prior to this offering, there has been no public market for our common stock. We have applied to list our common stock on the Nasdaq Global Market under the symbol "HLVX."

We are an "emerging growth company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements.

\_\_\_\_\_

	Per share	Total
Initial public offering price	\$ _____	\$ _____
Underwriting discounts and commissions(1)	\$ _____	\$ _____
Proceeds to HilleVax, Inc., before expenses	\$ _____	\$ _____

(1) See "Underwriting" for a description of the compensation payable to the underwriters.

\_\_\_\_\_

We have granted the underwriters an option for a period of 30 days to purchase up to \_\_\_\_\_ additional shares of our common stock.

Investing in our common stock involves a high degree of risk. See "[Risk factors](#)" beginning on page 14.

Neither the Securities and Exchange Commission nor any other state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on \_\_\_\_\_, 2022.

**J.P. Morgan**

**SVB Leerink**

**Stifel**

**Guggenheim Securities**

, 2022

## Table of contents

	<u>Page</u>
<a href="#">Prospectus summary</a>	1
<a href="#">Risk factors</a>	14
<a href="#">Special note regarding forward-looking statements</a>	79
<a href="#">Market and industry data</a>	80
<a href="#">Use of proceeds</a>	81
<a href="#">Dividend policy</a>	83
<a href="#">Capitalization</a>	84
<a href="#">Dilution</a>	86
<a href="#">Management's discussion and analysis of financial condition and results of operations</a>	89
<a href="#">Business</a>	104
<a href="#">Management</a>	146
<a href="#">Executive and director compensation</a>	155
<a href="#">Certain relationships and related person transactions</a>	170
<a href="#">Principal stockholders</a>	176
<a href="#">Description of capital stock</a>	178
<a href="#">Shares eligible for future sale</a>	184
<a href="#">Material United States federal income tax consequences to non-U.S. holders</a>	187
<a href="#">Underwriting</a>	191
<a href="#">Legal matters</a>	202
<a href="#">Experts</a>	202
<a href="#">Where you can find more information</a>	202
<a href="#">Index to combined financial statements</a>	F-1

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**Through and including \_\_\_\_\_, 2022 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.**

Neither we nor the underwriters have authorized anyone to provide you with information other than that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or of any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: we have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

## Prospectus summary

*This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the sections titled “Risk factors” and “Management’s discussion and analysis of financial condition and results of operations” and our combined financial statements and related notes included elsewhere in this prospectus, before making an investment decision. As used in this prospectus, unless the context otherwise requires, references to “we,” “us,” “our,” “the Company” and “HilleVax” refer to HilleVax, Inc., its subsidiary, and North Bridge V, Inc. and YamadaCo III, Inc. prior to the Merger.*

## 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 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 Vaccines, Inc. (Takeda) and its predecessor, LigoCyte Pharmaceuticals, Inc. (LigoCyte), which collectively generated safety data from more than 4,500 subjects and immunogenicity, or the ability of the vaccine to provoke an immune response, data from more than 2,200 subjects. These trials also generated 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 plan to initiate a Phase 2b clinical

trial in [redacted] to evaluate the safety, immunogenicity, and efficacy of HIL-214 in infants. We expect to report safety and immunogenicity data from this trial for the first 200 subjects in [redacted] and top-line data in [redacted]. We believe HIL-214 has the potential to be the first ever vaccine approved for norovirus-related illness and that it will help grow HilleVax into a leading global vaccines company.

**Our Pipeline**

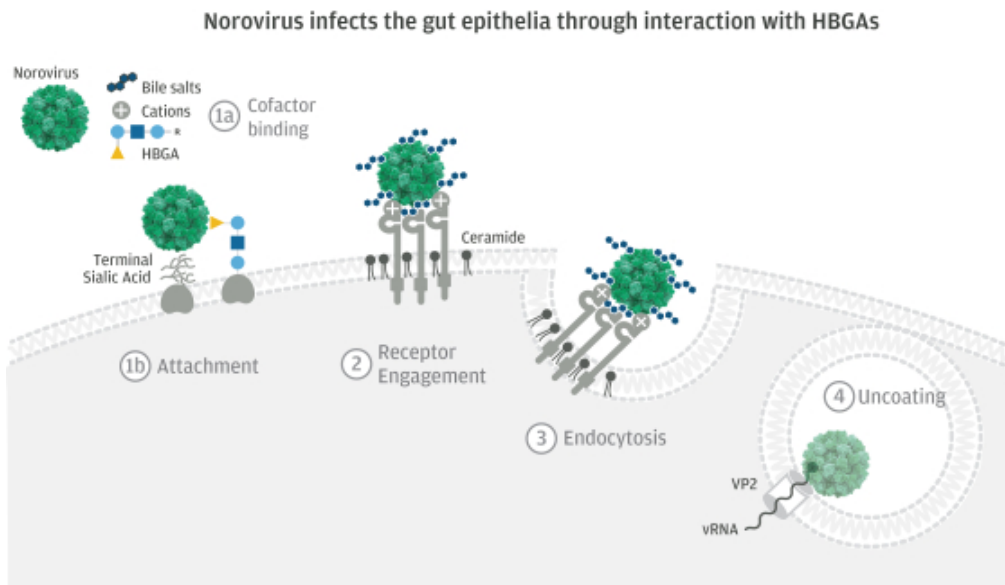
The following chart summarizes our current development programs.

Program <sup>1</sup>	Description	Disease	Target population	Age	Phase 1	Phase 2	Phase 3	Anticipated milestones
HIL-214	GI.1 / GI.4 VLP-based vaccine	Norovirus-related illness	Infants <sup>2</sup>	5 months	[Progress bar: Phase 1 to Phase 2]			Phase 2b trial initiation ( [redacted] 2022)
			Children <sup>2,3</sup>	2 – 9 years	[Progress bar: Phase 1 to Phase 2]			Immunobridging and/or efficacy studies after Phase 2b trial in infants
			Adults <sup>2,4</sup>	18 – 59 years	[Progress bar: Phase 1 to Phase 2]			
			Older adults <sup>2</sup>	≥ 60 years	[Progress bar: Phase 1 to Phase 2]			

1. All trials to date conducted by Takeda and Ligocyte. See page 5 for a table showing the completed clinical trials for HIL-214.
2. Completed Phase 2 trial(s) evaluating 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.

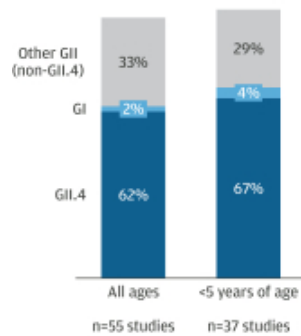
**Norovirus overview**

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, or the protein shell of a virus. 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 histo-blood group antigens (HBGAs), which are chains of simple sugars found on the epithelia of the respiratory, genitourinary, and digestive tracts, as well as in body fluids such as blood and saliva.



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.

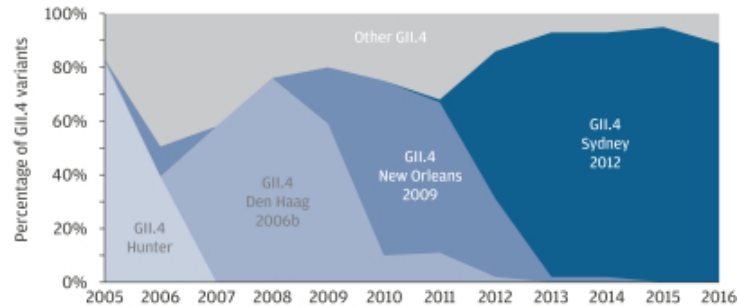
**Proportion of all norovirus genotypes reported, 2008-2014**



Adapted from Ahmed et al., 2014 and Hoa Tran et al., 2013

Data represent meta-analysis of 175 studies, totaling ~200k cases across 48 countries from 2008-2014

**Proportion of GII.4 variants reported, 2005-2016**



Adapted from van Beek et al., 2018

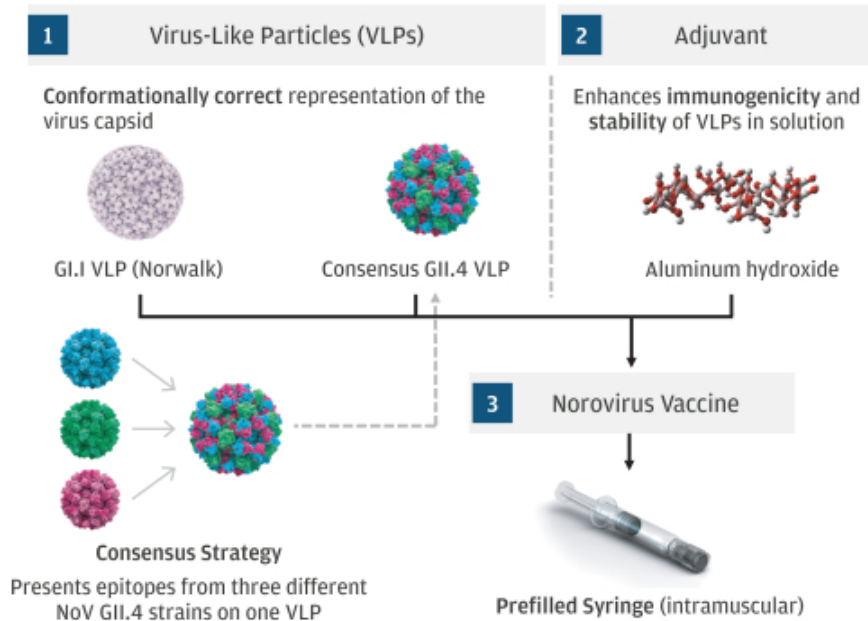
Data represent analysis of outbreak investigations and sporadic cases, ~17k in total, from 2005-2016 in Europe, Asia, Oceania and Africa

Norovirus is the most common cause of viral AGE worldwide and is characterized by symptoms, including 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. Up to 80% of children will experience a norovirus infection within one year of birth, with the majority of cases occurring between six months and two years of age. 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.

### **Our solution: HIL-214**

HIL-214 is a bivalent (containing two proteins) 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. VLPs are self-assembling structures that mimic the unique and repetitive geometric features that characterize the surface of a live virus. HIL-214 comprises VLPs for the two major genotypes of norovirus: GI.1 and GII.4. 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. 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 design contains VLPs for major genotypes GI.1 and GII.4**



### **HIL-214 clinical data and development plan**

HIL-214 has been extensively evaluated in nine Phase 1 and 2 clinical trials. Safety data generated across more than 4,500 subjects in these trials indicated that HIL-214 was well tolerated across all age groups and had an adverse event (AE) profile similar to that of other approved alum-adsorbed 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, drowsiness, diarrhea, and pain near the injection site. 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. 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).

**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	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/> <i>Challenge</i>	18 – 50 yrs	N/A <sup>1</sup>	N/A <sup>1</sup>
	LV03-104	1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		18 – 85 yrs	66	66
	LV03-105	1/2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/> <i>Challenge</i>	18 – 50 yrs	67	67
Takeda	NOR-210	2	<i>Generation of serum controls for assay validation</i>				18 – 49 yrs	50	50
	NOR-107	2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			18 – 64 yrs	418	418
	NOR-201	2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			18 – 49 yrs	425	425
	NOR-204	2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		18 – >85 yrs	311	311
	NOR-211	2b	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/> <i>Field study</i>	18 – 49 yrs	2,355	97
	NOR-202	2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		6 wks – 9 yrs	839	839
							<b>TOTAL:</b>	<b>4,531</b>	<b>2,273</b>

<sup>1</sup> Intranasal formulation of vaccine, not included in HIL-214 safety and immunogenicity subject numbers

Our near-term clinical development plan is focused on infants, a population in which norovirus is routinely circulating and infections are common. We plan to initiate a Phase 2b clinical trial in  to evaluate the safety, immunogenicity, and efficacy of HIL-214 in infants. The Phase 2b clinical trial will be the first clinical trial conducted by us, as all prior Phase 1 and 2 clinical trials were completed by Takeda. We expect to report a safety and immunogenicity analysis from this trial for the first 200 subjects in  and top-line data in . After conclusion of the Phase 2b trial in infants, we plan to proceed to a pivotal Phase 3 efficacy trial in infants. 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 nearly universally 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.

**Commercial opportunity**

The global vaccine market is estimated to have been over \$50 billion in 2020 and is expected to exceed \$100 billion by 2027. 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 more than \$1.6 billion in global sales in 2020. In the older adult market, we believe that Shingrix, a vaccine developed by GlaxoSmithKline to prevent shingles, is an analogue for HIL-214 due to the similarities in morbidity, mortality and economic burden between shingles and norovirus each before the introduction of a vaccine. Shingrix generated \$2.7 billion in sales in 2020. 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 team and investors***

Our company was founded by Frazier and Takeda Pharmaceuticals with the goal of developing and commercializing the first vaccine for norovirus-related illness. Our late co-founder, Tachi Yamada, M.D., was the former Chief Medical and Scientific Officer at Takeda Pharmaceuticals. Since our founding, we have assembled a distinguished group of executives, directors, and advisors with extensive experience in vaccine development, clinical trial operations, manufacturing, and commercialization, including prior experience developing HIL-214 at Takeda Pharmaceuticals. Our President, Chief Executive Officer, and Chairman, Rob Hersberg, M.D., Ph.D., was previously Executive Vice President and Chief Scientific Officer of Celgene and was subsequently Executive Vice President and Head of Business Development & Global Alliances and served as a member of the Executive Committee until the acquisition of Celgene by Bristol-Myers Squibb in 2019. David Socks, our Chief Financial Officer and Chief Business Officer, co-founded Arcutis, Cadence Pharmaceuticals, Incline Therapeutics, Passage Bio, and Phathom Pharmaceuticals, where he was the Chief Executive Officer through the company's initial public offering in 2019 and later served as interim Chief Financial Officer. Aditya Kohli, Ph.D., our Chief Operating Officer, co-founded Scout Bio, Passage Bio, and Phathom Pharmaceuticals and currently serves as the Chief Business Officer at Phathom and on the board of Scout Bio. Astrid Borkowski, M.D., Ph.D., our Chief Medical Officer, is the former VP, Head of Clinical Development at Takeda Pharmaceuticals' Vaccine Business Unit, where she oversaw the clinical development of all vaccine assets, including HIL-214. Paul Bavier, our General Counsel, Secretary, and Chief Administrative Officer, is the former General Counsel at VelosBio, Avedro, and Biodel.

Since our inception, we have raised approximately \$137.2 million in capital from various investors.

### **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:

- Advancing the clinical development of HIL-214 for the prevention of norovirus-caused AGE in infants.
- Expanding the development of HIL-214 to older populations and other high-risk groups.
- Commercializing HIL-214 in the United States.
- Seeking commercial partnerships to maximize the HIL-214 opportunity outside of the United States.
- Pursuing expansion strategies for HIL-214.
- In-licensing or acquiring additional products or technology platforms relevant to the prevention of other infectious diseases.

## Summary of risks related to our business

Our ability to execute our business strategy is subject to numerous risks, as more fully described in “Risk factors” immediately following this Prospectus Summary. These risks include, among others:

- 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.
- Our management, as of December 31, 2020, and our independent registered public accounting firm, in their report on our audited combined financial statements as of and for the year ended December 31, 2020, have concluded that there is substantial doubt as to our ability to continue as a going concern.
- We currently depend entirely on the success of HIL-214, which is our only 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.
- 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.
- Any difficulties or delays in the commencement or completion, or the termination or suspension, of our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- As an organization, we have never completed any clinical trials, and we may be unable to do so for HIL-214 or any future vaccine candidates.
- 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 clinical trials and preclinical studies. 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 future vaccine candidates may be delayed.
- 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 commercialization efforts.
- The commercial success of HIL-214 or any future 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 agencies.

- 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.
- Our business is subject to risks arising from the COVID-19 pandemic and other epidemic diseases.
- If we are unable to obtain, maintain and enforce patent protection for HIL-214 or any future 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 future vaccine candidates may be adversely affected.

## **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 (the Merger). References throughout this registration statement to HilleVax, Inc. include North Bridge V, Inc. and YamadaCo III, Inc. prior to the Merger. Our principal executive offices are located at 75 State Street, Suite 100 - #9995, Boston, Massachusetts 02109, and our telephone number is (617) 213-5054. Our website address is [www.hillevax.com](http://www.hillevax.com). The information contained in, or accessible through, our website does not constitute a part of this prospectus. We have included our website address as an inactive textual reference only. See Note 1 to our audited combined financial statements included elsewhere in this prospectus for further information on our organization and the basis of presentation of our combined financial statements.

We use our trademarks in this prospectus as well as trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this prospectus 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.

## **Implications of being an emerging growth company and a smaller reporting company**

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). As an emerging growth company, we may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- 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 of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (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 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 stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the closing of this offering, which such fifth anniversary will occur in 2026. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934 (the Exchange Act), our annual gross revenues exceed \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this prospectus and in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information in this prospectus and that we provide to our stockholders in the future may be different than what you might receive from other public reporting companies in which you hold equity interests.

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. 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. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. 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 the Sarbanes-Oxley Act.

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.

## The offering

<b>Common stock offered by us</b>	shares.
<b>Option to purchase additional shares</b>	The underwriters have been granted an option to purchase up to additional shares of common stock from us at any time within 30 days from the date of this prospectus.
<b>Common stock to be outstanding immediately after this offering</b>	shares (or shares if the underwriters exercise their option to purchase additional shares in full).
<b>Use of proceeds</b>	<p>We estimate that the net proceeds to us from this offering will be approximately \$ million (or approximately \$ million if the underwriters exercise their option to purchase additional shares in full) from the sale of the shares of common stock offered by us in this offering, assuming an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We intend to use the net proceeds of this offering, together with our existing cash, to fund the clinical development of HIL-214, including certain manufacturing activities, and for working capital and general corporate purposes. See the section titled "Use of proceeds."</p>
<b>Risk factors</b>	See the section titled "Risk factors" and other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
<b>Proposed Nasdaq Global Market symbol</b>	"HLVX"

The number of shares of our common stock to be outstanding after this offering is based on 5,488,000 shares of our common stock outstanding as of September 30, 2021, including 1,626,870 shares subject to forfeiture or our right of repurchase, and gives effect to the automatic conversion of \$139.5 million of aggregate principal amount, plus accrued interest thereon, of convertible promissory notes we issued in August 2021 (the August 2021 Notes), into an aggregate of shares of our common stock immediately prior to the closing of this offering (based on an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on , 2021), and excludes:

- 3,500,000 shares of common stock issuable to Takeda upon the exercise of an outstanding warrant (the Takeda Warrant), as of September 30, 2021, at an exercise price of \$0.0001 per share;
- shares of common stock reserved for future issuance under our 2022 Incentive Award Plan (the 2022 Plan), which will become effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the 2022 Plan); and

- \_\_\_\_\_ shares of common stock reserved for future issuance under our 2022 Employee Stock Purchase Plan (the ESPP), which will become effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the ESPP).

Unless otherwise indicated, all information contained in this prospectus assumes or gives effect to:

- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur immediately prior to the closing of this offering;
- the issuance of \_\_\_\_\_ shares of common stock upon the automatic conversion of the August 2021 Notes immediately prior to the closing of this offering (based on the assumed initial public price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover of this prospectus, and assuming the conversion occurs on \_\_\_\_\_, 2021);
- the expiration of the right granted to Takeda to receive an additional common stock warrant (the Takeda Warrant Right) upon the closing of this offering (based on an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover of this prospectus, as further described below in the section titled “Management’s discussion and analysis of financial condition and results of operations—Overview—License agreement with Takeda”);
- a 943.8776-for-1 forward stock split of our common stock effected on February 8, 2021;
- a subsequent \_\_\_\_\_-for-\_\_\_\_\_ forward stock split of our common stock to be effected before the closing of this offering;
- no exercise of the outstanding warrants described above; and
- no exercise by the underwriters of their option to purchase \_\_\_\_\_ additional shares of our common stock.

Each \$1.00 increase in the assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, would decrease the number of shares of our common stock issued upon conversion of the August 2021 Notes by \_\_\_\_\_ shares. Each \$1.00 decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share would increase the number of shares of our common stock issued upon conversion of the August 2021 Notes by \_\_\_\_\_ shares.

## Summary combined financial data

The following tables set forth a summary of our historical combined financial data as of, and for the periods ended on, the dates indicated. The combined financial statements include the accounts of our company, North Bridge V and YamadaCo III, all of which were entities under common control prior to the Merger, and our subsidiary. We have derived the summary combined statements of operations data for the period from January 8, 2019 (inception) through December 31, 2019 and the year ended December 31, 2020 from our audited combined financial statements included elsewhere in this prospectus. We have derived the summary combined statements of operations data for the nine months ended September 30, 2020 and 2021 and the summary combined balance sheet data as of September 30, 2021 from our unaudited combined financial statements included elsewhere in this prospectus. The unaudited combined financial statements have been prepared on a basis consistent with our audited combined financial statements included in this prospectus and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary to fairly state the financial information in those statements. You should read these data together with our combined financial statements and related notes included elsewhere in this prospectus and the section titled "Management's discussion and analysis of financial condition and results of operations." Our historical results for any prior period are not necessarily indicative of our future results.

(in thousands, except share and per share data)	Period from January 8, 2019 (inception) to December 31, 2019	Year ended December 31, 2020	Nine months ended September 30,	
			2020	2021 (unaudited)
<b>Statements of operations data:</b>				
Operating expenses:				
Research and development (includes related party amounts of \$0, \$0, \$0 and \$15, respectively)	\$ —	\$ —	\$ —	\$ 1,623
In-process research and development	—	—	—	37,666
General and administrative (includes related party amounts of \$424, \$467, \$361 and \$599, respectively)	633	1,295	850	3,064
Total operating expenses	633	1,295	850	42,353
Loss from operations	(633)	(1,295)	(850)	(42,353)
Other income (expense):				
Interest expense (includes related party amounts of \$(9), \$(29), \$(21) and \$(199), respectively)	(9)	(29)	(21)	(734)
Change in fair value of convertible promissory notes (includes related party amounts of \$(31) and \$(779), \$(513) and \$(1,435), respectively)	(31)	(779)	(513)	(1,392)
Change in fair value of warrant liabilities	—	—	—	(20,598)
Other income (expense)	—	—	—	(4)
Total other income (expense)	(40)	(808)	(534)	(22,728)
Net loss	\$ (673)	\$ (2,103)	\$ (1,384)	\$ (65,081)
Net loss per share, basic and diluted(1)	\$ (0.55)	\$ (0.81)	\$ (0.55)	\$ (20.62)
Weighted-average shares of common stock outstanding, basic and diluted(1)	1,223,006	2,598,266	2,519,910	3,156,879
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)(2)		\$		\$
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited)(2)				



## Table of Contents

- (1) See Note 1 to our combined financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the basic and diluted net loss per share and the number of shares used in the computation of the per share amounts.
- (2) See the section titled "Management's discussion and analysis of financial condition and results of operations—Unaudited pro forma net loss per share" for an explanation of the method used to calculate the pro forma net loss per share attributable to common stockholders, basic and diluted, and the number of shares used in the computation of the per share amounts.

(in thousands)	As of September 30, 2021		
	Actual (unaudited)	Pro forma(1) (unaudited)	Pro forma as adjusted(2) (3) (unaudited)
<b>Balance sheet data:</b>			
Cash	\$ 129,579	\$	\$
Working capital (deficit)(4)	(63,876)		
Total assets	130,167		
Convertible promissory notes payable at fair value (including accrued interest)	140,175		
Warrant liabilities	51,132		
Accumulated deficit	(67,857)		
Total stockholders' equity (deficit)	(63,497)		

- (1) Gives effect to (i) the automatic conversion of the August 2021 Notes into an aggregate of \_\_\_\_\_ shares of our common stock immediately prior to the closing of this offering (based on an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming the conversion occurs on \_\_\_\_\_, 2021), and (ii) the reclassification of the Takeda Warrant to stockholders' equity (deficit).
- (2) Gives effect to (i) the pro forma adjustments set forth in footnote (1) above and (ii) our sale of \_\_\_\_\_ shares of common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) Pro forma as adjusted balance sheet data is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) pro forma as adjusted cash, working capital, total assets and total stockholders' equity (deficit) by approximately \$ \_\_\_\_\_ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. A one million share increase (decrease) in the number of shares offered by us would increase or decrease pro forma as adjusted cash, working capital, total assets and total stockholders' equity (deficit) by approximately \$ \_\_\_\_\_ million, assuming that the assumed initial offering price to the public remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.
- (4) We define working capital as current assets less current liabilities. See our combined financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

## 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 in this prospectus, including our financial statements and related notes included elsewhere in this prospectus and the section titled "Management's discussion and analysis of financial condition and results of operations" before making an investment decision. 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. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See "Special note regarding forward-looking statements."*

### **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 planned clinical trials of HIL-214. We have not yet submitted an IND or its equivalent to the 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 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 \$0.7 million and \$2.1 million for the period from January 8, 2019 (inception) to December 31, 2019 and the year ended December 31, 2020, respectively, and \$65.1 million for the nine months ended September 30, 2021. We have financed our operations to date through the issuance of convertible promissory notes. 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 future vaccine

## [Table of Contents](#)

candidates 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 and any future 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 planned clinical trials for HIL-214 and potentially seek regulatory approval for HIL-214 and any future 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 whom 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). If we obtain regulatory approval for HIL-214 or any future 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 future vaccine candidates. Furthermore, following the completion of this offering, we expect to incur additional costs associated with operating as a public company. We do not have any committed external source of funds.

As of September 30, 2021, we had cash of \$129.6 million. Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash, will enable us to fund our operations through at least . 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. The net proceeds of this offering, together with our existing cash and restricted cash, will not be sufficient to complete development of HIL-214, or any future vaccine candidate, and after this offering, we will require substantial capital in order to advance HIL-214 and any future vaccine candidates through clinical trials, regulatory approval and commercialization. Accordingly, we will need to obtain substantial additional funding

## [Table of Contents](#)

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 future 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 planned clinical trials of HIL-214 and preclinical studies or clinical trials of 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 future 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 any future vaccine candidates;
- any delays and cost increases that may result from the COVID-19 pandemic;
- 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 future 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.

## Table of Contents

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 future vaccine candidates. If approved, HIL-214 and any future 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.

***Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, 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, 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. 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.

***Our management, as of December 31, 2020, and our independent registered public accounting firm, in their report on our audited combined financial statements as of and for the year ended December 31, 2020, have concluded that there is substantial doubt as to our ability to continue as a going concern.***

Our audited combined financial statements for the year ended December 31, 2020 were prepared assuming that we will continue as a going concern. The going concern basis of presentation assumes that we will continue in operation for the foreseeable future and will be able to realize our assets and satisfy our liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from our inability to continue as a going concern. As of December 31, 2020, our management concluded that, based on our expected operating losses, negative cash flows and maturities of outstanding convertible promissory notes, there is substantial doubt about our ability to continue as a going concern for the twelve months after the date the combined financial statements were issued. Our ability to continue as a going concern is subject to our ability to obtain sufficient financing. If we cannot continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our combined financial statements, and it is likely that our stockholders may lose some or all of their investment in us.

After this offering, we may not raise the funding we require such that substantial doubt about our ability to continue as a going concern continues. If we seek additional financing to fund our business activities in the

future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

## **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 only 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, 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 lead 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 planned clinical trials. The success of HIL-214 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 of HIL-214, 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 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;
- 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 EMA, 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 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
- acceptance of our products, if approved, by patients, the medical community and third-party payors.

## [Table of Contents](#)

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 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. 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 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, EMA, 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.



## [Table of Contents](#)

As a result, we cannot be certain that our 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.

***Any difficulties or delays in the commencement or completion, or the termination or suspension, of our 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 future 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 plan to initiate a Phase 2b clinical trial. Before we can initiate clinical trials for any future 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 authorization 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 and any future 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 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 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;

## Table of Contents

- 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 pandemic;
- 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, health reasons or otherwise resulting from the COVID-19 pandemic;
- insufficient incidence of norovirus infection to allow us to evaluate the endpoints in our clinical trials of HIL-214, including lower incidence due to social changes resulting from the COVID-19 pandemic;
- individuals choosing an alternative product for the indication for which we are developing HIL-214 or any future 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 future 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.

Certain of our clinical trials are also being designed based on the learnings from previously completed clinical trials conducted by Takeda. For example, we have designed our planned Phase 2b clinical trial for HIL-214 based on the learnings from the NOR-211 Phase 2b study, the NOR-202 Phase 2 study, as well as preliminary feedback Takeda received from the FDA and the EMA. Although we do not currently expect the FDA to require us to conduct additional clinical trials before proceeding to the Phase 2b clinical trial, there is some risk that the FDA may ask questions or require additional information in order for us to advance to a Phase 2b clinical trial.

Further, conducting clinical trials in foreign countries, as we plan to do for HIL-214 and may do for future 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 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 future 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 future 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 or any future 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 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.

In addition, the process of finding and recruiting subjects may prove costly. The timing of our clinical trials depends, in part, on the speed at which we can recruit subjects to participate in our trials, as well as completion of required follow-up periods. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. If subjects are unwilling or unable to participate in our trials for any reason, including the existence of concurrent clinical trials for similar target populations, negative perceptions of vaccines generally or of any of our vaccine candidates in particular, the availability of approved or authorized therapies, the effects of the COVID-19 pandemic, or the fact that enrolling in our trials may prevent subjects from taking a different product, or we otherwise have difficulty enrolling a sufficient number of subjects, the timeline for recruiting subjects, conducting trials and obtaining regulatory approval of our vaccine candidates may be delayed. Our inability to enroll a specified number of subjects for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, we rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our preclinical studies and clinical trials. Though we have entered into agreements governing their services, we will have limited influence over their actual performance.

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 future vaccine candidates.***

We will need to successfully complete our planned clinical trials in order to seek FDA, EMA or comparable foreign regulatory approval to market HIL-214 or any future vaccine candidates. Carrying out clinical trials and the submission of a successful BLA or MAA is a complicated process. We plan to initiate a Phase 2b clinical trial of HIL-214 in infants in the first quarter of 2022. While Takeda previously conducted both Phase 1 and 2 clinical trials of HIL-214, we have not previously submitted an IND or completed any clinical trials and have not previously submitted a BLA, MAA or other comparable foreign regulatory submission. 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 future 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 future vaccine candidates.

***Use of HIL-214 or any future 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 future 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, prospectus, operating results and financial condition.

Moreover, if HIL-214 or any future 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 planned Phase 2b clinical trial in infants and 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 future 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

## [Table of Contents](#)

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 future 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 future 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 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 EMA in Europe.

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

## [Table of Contents](#)

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, EMA 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 future vaccine candidates either prior to approval or post-approval, or may object to elements of our clinical development program.

The FDA, EMA 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 future 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 future vaccine candidates, which would significantly harm our business, results of operations and prospects.

## [Table of Contents](#)

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 future 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. In addition, immunobridging to older adults may be particularly challenging given the incidence rate seen in this population. 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 a result of our decision to pursue a given age group, formulation or indication, 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 future 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 future 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 be affected by the COVID-19 pandemic. For example, measures taken that may limit social interaction or prevent reopening of high-transmission settings may reduce incidence rates. 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 future 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 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 future vaccine candidates may cause such candidates to perform

differently and affect the results of future clinical trials conducted with the altered materials. We plan to review and report safety and immunogenicity data from the first approximately 200 subjects in our planned Phase 2b clinical trial to assess HIL-214 manufactured using this new process. 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 future 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 and other government agencies 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 and other government agencies 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 agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, 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, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products. Subsequently, on March 18, 2020 the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized or deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. In addition, regulatory agencies such as the FDA and EMA slowed down the review of non-COVID vaccine-related efforts since 2020 in order to handle the workload and priority needed for review of COVID-related vaccines. 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. For additional information on the Takeda License, see "Business—License agreement with Takeda."

***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 future vaccine candidates may be delayed.***

We depend on third parties to conduct our preclinical studies and clinical trials for HIL-214 and any future 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, EMA and comparable foreign regulatory authorities for HIL-214 and any future 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 produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials or recall batches of our vaccine candidate, 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

## [Table of Contents](#)

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 planned Phase 2b clinical trial in infants. In addition, we are exploring options for clinical supply of HIL-214 from additional third-party contract manufacturers for future clinical trials. As a result, we currently rely, and expect to continue to rely, on third parties for the manufacture of HIL-214 and related raw materials for clinical development, as well as for commercial manufacture if HIL-214 or any future vaccine candidates receives marketing approval. The facilities used by third-party manufacturers to manufacture HIL-214 must be approved 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 requirements for manufacture of products. In addition, we have no control over the ability of third-party manufacturers to 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 for use in future clinical trials has a shelf life that may expire prior to the full enrollment of our 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, 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 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

## [Table of Contents](#)

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 future vaccine candidates that we may develop may compete with other vaccine candidates and products for access to such manufacturers and manufacturing facilities. In addition, the COVID-19 pandemic has reduced manufacturing capacity worldwide and limited access to materials needed to manufacture key components of HIL-214. 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 future 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 future 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. For example, in June 2020, the FDA issued a warning letter to Takeda following a routine inspection of aseptic (sterile) drug product manufacturing at Takeda's manufacturing facility located in Hikari, Yamaguchi (the Hikari Facility). Takeda also manufactures HIL-214, an aseptic product, at the Hikari Facility. The warning letter stated that the FDA was not satisfied with Takeda's response to an FDA Form 483 issued to Takeda following the inspection and cited significant violations of cGMP for finished aseptic pharmaceuticals. We have not experienced any clinical supply constraints to date as a result of these issues and the issues relating to the Hikari Facility were closed by the FDA in October 2021. We currently do not expect that the issues relating to the Hikari Facility will have an effect on our ongoing or future clinical trials. 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

## [Table of Contents](#)

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 future vaccine candidates;
- delay in submitting regulatory applications, or receiving marketing approvals, for HIL-214 or any future 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 future vaccine candidates; and
- in the event of approval to market and commercialize HIL-214 or any future 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 future 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 Takeda 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 future 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 future 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 future 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;



## Table of Contents

- 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 future 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 future vaccine candidates**

***Even if we receive regulatory approval for HIL-214 and any future 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 future 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 future 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 future 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 future 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 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 future 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.

***HIL-214 and any future 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. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. We believe that HIL-214 or any future 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 future 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 future vaccine candidates may not be commercially successful. Even if HIL-214 or any future 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 future 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;

## Table of Contents

- 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 future vaccine candidates. If HIL-214 or any future 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 future 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 future 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 future 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 future 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 European Union 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 future 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 future 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 including China National Biotec, Chongqing Zhifei Biological, Icon Genetics 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 future vaccine

## [Table of Contents](#)

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 future 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 future 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 future 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 future 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,

## [Table of Contents](#)

commercial sales, pricing and distribution of HIL-214 and any future 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 ongoing 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 or any future vaccine candidates, which may change from time to time;
- the timing and success or failure of preclinical studies or clinical trials for HIL-214 or any future vaccine candidates or competing vaccine candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;



## Table of Contents

- coverage and reimbursement policies with respect to HIL-214 or any future vaccine candidates, if approved, and potential future drugs that compete with our products;
- the cost of manufacturing HIL-214 or any future vaccine candidates, which may vary depending on the quantity of production and the terms of our agreements with Takeda 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;
- 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 November 15, 2021, we had 15 full-time employees, including 9 employees engaged in research and development. As we continue development and pursue the potential commercialization of HIL-214 and any future 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 future vaccine candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

***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), teaching hospitals and other healthcare providers, as well as ownership and investment interests held by such healthcare professionals and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives; 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 of pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and privacy 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 future 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

## [Table of Contents](#)

that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell HIL-214 and any future 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, or other efforts to challenge the ACA, if any, will impact the ACA or 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 of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, 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 former Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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 future 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 future vaccine candidates, if approved.

***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 planned clinical trials of HIL-214 and any future 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 future 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 future 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 future 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 future 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 privacy and data security laws and contractual obligations, which could increase compliance costs, and our actual or perceived failure to comply with such laws and obligations 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 planned 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 data. 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 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) recently passed in California. The CPRA will impose 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 will also create 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 will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Other states are exploring their own laws, which may or may not be similar to the CCPA or the CPRA. 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). 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. The GDPR also confers a private right of action in some circumstances on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. Among other things, the GDPR requires the establishment of a lawful basis for the processing of data, imposes requirements relating to the consent of the individuals to whom the personal data relates, including detailed notices for clinical trial subjects and investigators, as well as requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities. In

addition, the GDPR increases the scrutiny of transfers 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. For example, on July 16, 2020, the Court of Justice of the European Union (CJEU) invalidated the EU-US Privacy Shield Framework (Privacy Shield) under which personal data could be transferred from the EEA to United States entities that had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on the standard contractual clauses alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals, and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The European Commission issued revised standard contractual clauses on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised standard contractual clauses must be used for relevant new data transfers beginning on September 27, 2021 and existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. 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 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, 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. The relationship between the United Kingdom and the European Union and the EEA in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews or extends that decision.

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. Many state legislatures have adopted legislation that regulates how businesses operate online, including measures relating to privacy, data security and data breaches. Laws in all U.S. states require businesses to provide notice to customers whose personally identifiable information has been disclosed as a result of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly.



## [Table of Contents](#)

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 internal 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, infrastructure and data 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.

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 are working 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. 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, 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 computer 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 future 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.



Further, despite the implementation of security measures, our internal technology systems (including infrastructure) and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, computer viruses, cybersecurity threats (such as ransomware attacks, denial-of-service attacks, cyber-attacks or cyber-intrusions over the Internet, hacking, phishing and other social engineering attacks), unauthorized access or use, natural disasters, terrorism, war and telecommunication and electrical failures. Such information technology systems are additionally vulnerable to security incidents from inadvertent or intentional actions by our employees, contractors, consultants or other third parties. 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. We do not currently hold cybersecurity insurance, and the costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses.

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.

***Our business is subject to risks arising from the COVID-19 pandemic and other epidemic diseases.***

The COVID-19 worldwide pandemic has presented substantial public health and economic challenges and is affecting our employees, clinical trial subjects, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions have taken, and are continuing to take, actions in an effort to slow the spread of COVID-19 and variants of the virus, including issuing varying forms of “stay-at-home” orders, and restricting business functions outside of one’s home. In response, our administrative employees have worked remotely and we have limited the number of staff in our research and development laboratories. To date we have not experienced material disruptions in our business operations. However, while it is not possible at this time to estimate the impact that COVID-19 could have on our business in the future, particularly as we advance HIL-214 through clinical development, the continued spread of COVID-19 and the measures taken by the governmental authorities, and any future epidemic disease outbreaks, 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. The COVID-19 pandemic

and any future epidemic disease outbreak 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. The COVID-19 pandemic and mitigation measures have had and may continue to have, and any future epidemic disease outbreak may have, an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus, including the identification of new variants, and the actions to contain its impact.

***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 future 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 future 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 future 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 is, 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 future 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. For additional information on the Takeda License, see “Business—License agreement with Takeda.”

***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 future 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 future 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. For additional information on the anticipated expiration dates of our licensed patents, see "Business—Intellectual Property."

***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 future 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. For additional information on the anticipated expiration dates of our licensed patents, see “Business—Intellectual Property.”

***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 future 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 future 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 be 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 future 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 future 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 future 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 future 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 future 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 future 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, this offering and being a public company**

***There has been no public market for our common stock. An active, liquid and orderly market for our common stock may not develop, and you may not be able to resell your common stock at or above the initial public offering price.***

Prior to this offering, there has been no public market for our common stock. Although we have applied to list our common stock on the Nasdaq Global Market (Nasdaq), an active trading market for our common stock may never develop or may not be sustained following this offering. We and the representatives of the underwriters will determine the initial public offering price of our common stock through negotiation. This price will not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. In addition, an active trading market may not develop following the consummation of this offering or, if it is developed, may not be sustained. 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 initial public offering price. 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;

## Table of Contents

- our ability to enroll subjects in our future clinical trials;
- regulatory approval of HIL-214 or any future 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, many of which are beyond our control;
- 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.

***We may allocate the net proceeds from this offering in ways of which you and other stockholders may not approve.***

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in "Use of proceeds." Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from

## [Table of Contents](#)

their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment, and the failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected results, which could cause our stock price to decline.

### ***You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase.***

The initial public offering price of our common stock will be substantially higher than the pro forma as adjusted net tangible book value per share of our outstanding common stock immediately after the completion of this offering. Purchasers of common stock in this offering will experience immediate dilution of approximately \$            per share, assuming an initial public offering price of \$            per share, which is the midpoint of the price range set forth on the cover of this prospectus. For a further description of the dilution that you will experience immediately after this offering, see "Dilution."

### ***After this offering, our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to significantly influence all matters submitted to stockholders for approval.***

Following the completion of this offering, our executive officers, directors and greater than 5% stockholders, in the aggregate, will own approximately    % of our outstanding common stock (assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options, warrants or other rights, and without giving effect to any potential purchases by such persons in this offering). As a result, such persons, acting together, will 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.

### ***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. 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.

## [Table of Contents](#)

Based on shares of common stock outstanding as of September 30, 2021, upon the closing of this offering, we will have outstanding a total of \_\_\_\_\_ shares of common stock, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options, warrants or other rights. Of these shares, only the \_\_\_\_\_ shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable, without restriction, in the public market immediately following this offering, unless they are purchased by one of our affiliates.

In addition, immediately following the completion of this offering, Takeda will beneficially own \_\_\_\_\_ % of our outstanding shares of common stock, including 3,500,000 shares of common stock issuable pursuant to the Takeda Warrant (or \_\_\_\_\_ % if the underwriters exercise their option to purchase additional shares in full). The sale by Takeda of a substantial number of shares after this offering, or a perception that such sales could occur, could significantly reduce the market price of our common stock.

Our directors and officers and holders of substantially all of our outstanding securities have entered into lock-up agreements with the underwriters pursuant to which they may not, with limited exceptions, for a period of 180 days from the date of this prospectus, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of J.P. Morgan Securities LLC and SVB Leerink LLC. The underwriters may permit our officers, directors and other securityholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements at any time in their sole discretion. See "Underwriting." Sales of these shares, or perceptions that they will be sold, could cause the trading price of our common stock to decline.

After the lock-up agreements expire, up to an additional \_\_\_\_\_ shares of common stock will be eligible for sale in the public market, of which \_\_\_\_\_ shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act, in each case based on shares of common stock outstanding as of September 30, 2021 and without giving effect to any potential purchases by such persons in this offering.

In addition, promptly following this offering, we intend to file one or more registration statements on Form S-8 under the Securities Act registering the issuance of approximately \_\_\_\_\_ shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and the restrictions of Rule 144 in the case of our affiliates. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of \_\_\_\_\_ shares of our outstanding common stock, or approximately \_\_\_\_\_ % of our total outstanding common stock based on shares outstanding as of September 30, 2021, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting and the 180-day lock-up agreements described above. In addition, upon the closing of this offering Takeda will be entitled to the same rights with respect to the registration of 3,500,000 shares of our common stock underlying the Takeda Warrant. See "Description of capital stock—Registration rights." Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

***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 this offering.

## [Table of Contents](#)

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 \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. 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 have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. 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 charter 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 that will be in effect immediately prior to the consummation of this offering will 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



## [Table of Contents](#)

management without the consent of our board of directors. The provisions in our charter documents will 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 and amended and restated bylaws will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the 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 will also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees 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 will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.***

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Exchange Act, which will require, 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 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.

We expect the rules and regulations applicable to public companies to substantially 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.

***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 future 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 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, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, 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 this offering 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, if any, until such unused losses expire (if at all). We had no material net operating loss carryforwards as of December 31, 2020.

Under the Tax Cuts and Jobs Act (the Tax Act), federal NOL carryforwards generated in periods after December 31, 2017, may be carried forward indefinitely. The deductibility of federal NOL carryforwards, particularly for tax years beginning after December 31, 2020, may be limited. It is uncertain if and to what extent various states will conform to the Tax Act or the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act). In addition, our NOL carryforwards are subject to review and possible adjustment by the Internal Revenue Service (IRS), and state tax authorities. Under Section 382 of the Internal Revenue Code (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 certain cumulative changes in the ownership of our company. An "ownership change" pursuant to Section 382 of the Code 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 this offering 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 this offering. 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 U.S. tax law may materially adversely affect our financial condition, results of operations and cash flows.***

On March 27, 2020, the CARES Act was signed into law to address the COVID-19 crisis. The CARES Act is an approximately \$2 trillion emergency economic stimulus package that includes numerous U.S. federal income tax provisions, including the modification of: (i) NOL rules, (ii) the alternative minimum tax refund and (iii) business interest deduction limitations under Section 163(j) of the Code.

The Tax Act also significantly changed the U.S. federal income taxation of U.S. corporations. The Tax Act remains unclear in many respects and has been, and may continue to be, the subject of amendments and technical corrections, as well as interpretations and implementing regulations by the IRS, which have lessened or increased certain adverse impacts of the Tax Act and may continue to do so in the future. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. We continue to work with our tax advisors and auditors to determine the full impact the Tax Act and the CARES Act will have on us.

Congress may enact additional legislation in connection with the COVID-19 pandemic, and as a result of changes in the U.S. presidential administration and control of the U.S. Senate, additional tax legislation may also be enacted, which could have an impact on our company. We urge our investors to consult with their legal and tax advisors with respect to the Tax Act, the CARES Act, and possible changes in U.S. 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 will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We do not currently have and

may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, 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 begin 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.

## Special note regarding forward-looking statements

This prospectus contains forward-looking statements. All statements other than statements of historical fact contained in this prospectus, 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 planned and potential clinical trials and preclinical studies for HIL-214 and any future vaccine candidates, the timing and likelihood of regulatory filings and approvals for HIL-214 and any future vaccine candidates, our ability to commercialize our vaccine candidates, if approved, the impact of COVID-19 on our business, the pricing and reimbursement of our vaccine candidates, if approved, the potential to develop future vaccine candidates, the potential benefits of strategic collaborations and our intent to enter into any strategic arrangements, the timing and likelihood of success, 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.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus 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, results of operations and prospects. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections titled “Risk factors” and “Management’s discussion and analysis of financial condition and results of operations” and elsewhere in this prospectus. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, and therefore should not be considered predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we undertake no obligation to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See the section titled “Where you can find more information.”

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are inherently uncertain and are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information.



## **Market and industry data**

We obtained the industry, market and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information in addition to research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in the section titled "Risk factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

## Use of proceeds

We estimate that the net proceeds to us from this offering will be approximately \$ \_\_\_\_\_ million (or approximately \$ \_\_\_\_\_ million if the underwriters exercise their option to purchase additional shares in full) from the sale of the shares of common stock offered by us in this offering, assuming an initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately \$ \_\_\_\_\_ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. A one million share increase (decrease) in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering by approximately \$ \_\_\_\_\_ million, assuming that the assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the initial public offering price or the number of shares by these amounts would have a material effect on our intended uses of the net proceeds from this offering, although it may accelerate the time at which we will need to seek additional capital.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets. We intend to use approximately \$ \_\_\_\_\_ of the net proceeds from this offering to fund the clinical development of HIL-214, including certain manufacturing activities, and the remainder for working capital and general corporate purposes.

We may also use a portion of the remaining net proceeds to in-license, acquire or invest in complementary businesses, technologies, products or assets, although we have no current agreements, commitments or understandings to do so.

Based on our current operating plan, we believe our existing cash, together with the estimated net proceeds from this offering, will be sufficient to meet our anticipated cash requirements through at least the next \_\_\_\_\_ months. In particular, we expect that the net proceeds from this offering will allow us to complete \_\_\_\_\_. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. The net proceeds of this offering, together with our existing cash, will not be sufficient to complete development of HIL-214, and after this offering, we will require substantial capital in order to advance HIL-214 and any future vaccine candidates through clinical trials, regulatory approval and commercialization.

Our expected use of existing cash and our net proceeds from this offering represent our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. Predicting the costs necessary to develop vaccine candidates can be difficult and we will need substantial additional capital to complete our clinical development of HIL-214 and any future vaccine candidates. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress and costs of our development activities, the status of and results from clinical trials, as well as the status and results from our current and any future collaborations with third parties for HIL-214 and any future vaccine candidates, and any unforeseen cash needs.

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[Table of Contents](#)

Our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of those net proceeds. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business. Pending these uses, we plan to invest these net proceeds in short-term, interest bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States.

## **Dividend policy**

We have never declared or paid, and do not anticipate declaring or paying in the foreseeable future, 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. 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.

## Capitalization

The following table sets forth our cash and capitalization as of September 30, 2021:

- on an actual basis;
- on a pro forma basis, giving effect to (i) the automatic conversion of the August 2021 Notes into an aggregate of \_\_\_\_\_ shares of our common stock immediately prior to the closing of this offering (based on an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and assuming the conversion occurs on \_\_\_\_\_, 2021), (ii) the reclassification of the Takeda Warrant to stockholders' equity (deficit), and (iii) the filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to reflect (i) the pro forma adjustments set forth above and (ii) our sale of \_\_\_\_\_ shares of common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information in this table together with our combined financial statements and related notes included elsewhere in this prospectus and the section titled "Management's discussion and analysis of financial condition and results of operations."

(in thousands, except share and per share data)	As of September 30, 2021		
	Actual (unaudited)	Pro forma (unaudited)	Pro forma as adjusted(1) (unaudited)
Cash	\$ 129,579	\$	\$
Convertible promissory notes payable at fair value (including accrued interest)	\$ 140,175	\$	\$
Warrant liabilities	51,132		
Stockholders' equity (deficit):			
Preferred stock, par value \$0.0001 per share; no shares authorized, issued and outstanding, actual; _____ shares authorized and no shares issued or outstanding pro forma and pro forma as adjusted	—		
Common stock, par value \$0.0001 per share; 10,000,000 shares authorized, 5,488,000 shares issued and 3,861,130 shares outstanding (excluding 1,626,870 shares subject to forfeiture or repurchase), actual; _____ shares authorized pro forma and pro forma as adjusted; _____ shares issued and _____ shares outstanding (excluding 1,626,870 shares subject to forfeiture or repurchase), pro forma; _____ shares issued and _____ shares outstanding (excluding 1,626,870 shares subject to forfeiture or repurchase), pro forma as adjusted	—		
Additional paid-in capital	4,360		
Accumulated deficit	(67,857)		
Total stockholders' equity (deficit)	(63,497)		
Total capitalization	\$ 127,810	\$	\$

(1) The pro forma as adjusted information set forth above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per

## Table of Contents

share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. A one million share increase (decrease) in the number of shares offered by us at the assumed initial public offering price per share of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately \$ million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The table above is based on the number of shares of common stock outstanding as of September 30, 2021 and excludes:

- 3,500,000 shares of common stock issuable to Takeda upon the exercise of the Takeda Warrant, as of September 30, 2021, at an exercise price of \$0.0001 per share;
- shares of common stock reserved for future issuance under the 2022 Plan, which will become effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the 2022 Plan); and
- shares of common stock reserved for future issuance under the ESPP, which will become effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the ESPP).

Each \$1.00 increase in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would decrease the number of shares of our common stock issued upon conversion of the August 2021 Notes by shares. Each \$1.00 decrease in the assumed initial public offering price of \$ per share would increase the number of shares of our common stock issued upon conversion of the August 2021 Notes by shares.

## Dilution

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

As of September 30, 2021, our historical net tangible book value (deficit) was \$(63.5) million, or \$(11.57) per share of our common stock, based on 5,488,000 shares of common stock outstanding as of such date, including 1,626,870 shares subject to forfeiture or our right of repurchase as of such date. Our historical net tangible book value (deficit) per share represents the amount of our total tangible assets less total liabilities, divided by the total number of shares of common stock outstanding at September 30, 2021.

After giving effect to (i) the automatic conversion of the August 2021 Notes into an aggregate of \_\_\_\_\_ shares of our common stock immediately prior to the closing of this offering (based on an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on \_\_\_\_\_, 2021), and (ii) the reclassification of the Takeda Warrant to stockholders' equity (deficit), our pro forma net tangible book value as of September 30, 2021 would have been approximately \$ \_\_\_\_\_ million, or approximately \$ \_\_\_\_\_ per share of our common stock.

After giving further effect to the sale of \_\_\_\_\_ shares of our common stock that we are offering at the assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2021 would have been \$ \_\_\_\_\_ million, or approximately \$ \_\_\_\_\_ per share. This amount represents an immediate increase in pro forma net tangible book value of \$ \_\_\_\_\_ per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately \$ \_\_\_\_\_ per share to new investors participating in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors. The following table illustrates this dilution (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Assumed initial public offering price per share	\$
Historical net tangible book value (deficit) per share at September 30, 2021	\$(11.57)
Pro forma increase in historical net tangible book value (deficit) per share as of September 30, 2021 attributable to the pro forma adjustments described above	_____
Pro forma net tangible book value per share as of September 30, 2021	_____
Increase in pro forma net tangible book value per share attributable to investors participating in this offering	_____
Pro forma as adjusted net tangible book value per share after this offering	_____
Dilution per share to new investors participating in this offering	\$

A \$1.00 increase in the assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, would decrease the number of shares of our common stock issued upon conversion of the August 2021 Notes by \_\_\_\_\_ shares, and would increase the pro forma as adjusted net tangible book value per share after this offering by approximately \$ \_\_\_\_\_, and decrease the dilution in pro forma net tangible book value per share to new investors by approximately \$ \_\_\_\_\_, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting



## [Table of Contents](#)

the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. A \$1.00 decrease in the assumed initial public offering price of \$ per share would increase the number of shares of our common stock issued upon conversion of the August 2021 Notes by shares, and would decrease the pro forma as adjusted net tangible book value per share after this offering by approximately \$ , and increase the dilution in pro forma net tangible book value per share to new investors by approximately \$ , assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us.

We may also increase or decrease the number of shares we are offering. An increase of one million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase our pro forma as adjusted net tangible book value per share after this offering by approximately \$ and decrease the dilution to investors participating in this offering by approximately \$ per share, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. Similarly, a decrease of one million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value per share after this offering by approximately \$ and increase the dilution to investors participating in this offering by approximately \$ per share, assuming the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us.

If the underwriters exercise their option to purchase up to additional shares of our common stock in full in this offering, the pro forma as adjusted net tangible book value after the offering would be \$ per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be \$ per share and the dilution per share to new investors would be \$ per share, in each case assuming an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus.

If the Takeda Warrant had been exercised as of September 30, 2021, the pro forma as adjusted net tangible book value after this offering would be approximately \$ million, or approximately \$ per share, and total dilution per share to new investors would be approximately \$ per share.

The following table summarizes, on a pro forma as adjusted basis as of September 30, 2021, the number of shares of common stock purchased or to be purchased from us, the total consideration paid or to be paid to us in cash and the average price per share paid by existing stockholders for shares issued prior to this offering and the price to be paid by new investors in this offering. The calculation below is based on the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table below shows, investors participating in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%	\$	%	\$
Investors participating in this offering					\$
Total		100.0%	\$	100.0%	

[Table of Contents](#)

If the underwriters exercise their option to purchase additional shares of our common stock in full:

- the percentage of shares of common stock held by existing stockholders before this offering will decrease to approximately \_\_\_\_\_ % of the total number of shares of our common stock outstanding after this offering; and
- the number of shares held by new investors participating in this offering will increase to \_\_\_\_\_, or approximately \_\_\_\_\_ % of the total number of shares of our common stock outstanding after this offering.

The foregoing tables and calculations exclude:

- 3,500,000 shares of common stock issuable to Takeda upon the exercise of the Takeda Warrant, as of September 30, 2021, at an exercise price of \$0.0001 per share;
- \_\_\_\_\_ shares of common stock reserved for future issuance under the 2022 Plan, which will become effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the 2022 Plan); and
- \_\_\_\_\_ shares of common stock reserved for future issuance under the ESPP, which will become effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the ESPP).

To the extent any outstanding warrants or other rights are exercised, or we issue additional equity or convertible securities in the future, there will be further dilution to new investors.

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

*The following discussion and analysis should be read in conjunction with our combined financial statements and related notes included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth in the section titled "Risk factors" and elsewhere in this prospectus. You should carefully read the "Risk factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special note regarding forward-looking statements."*

### Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines. Our initial program, HIL-214, is a VLP-based vaccine candidate for the prevention of moderate-to-severe 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. These trials also generated 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 IND was transferred to us from Takeda, under which we plan to initiate a Phase 2b clinical trial in \_\_\_\_\_ to evaluate the safety, immunogenicity, and efficacy of HIL-214 in infants. We expect to report safety and immunogenicity data from this trial for the first 200 subjects in \_\_\_\_\_ and top-line data in \_\_\_\_\_. 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 our planned 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. As of December 31, 2020 and September 30, 2021, we had cash of \$0.5 million and \$129.6 million, respectively. From inception to September 30, 2021, we raised aggregate gross proceeds of \$137.2 million from the issuance of convertible promissory notes.

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 period from January 8, 2019 (inception) to December 31, 2019 and the year ended December 31, 2020 were \$0.7 million and \$2.1 million, respectively. For the nine months ended September 30, 2021 our net loss was \$65.1 million. As of September 30, 2021, we had an accumulated deficit of \$67.9 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

## [Table of Contents](#)

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, and incur additional costs associated with operating as a public company.

Based on our current operating plan, we believe that our existing cash, together with the estimated net proceeds from this offering, will be sufficient to meet our anticipated cash requirements through at least the next 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, 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.

The global COVID-19 pandemic continues to evolve, and we will continue to monitor the COVID-19 situation closely. The extent of the impact of the COVID-19 pandemic on our business, operations and clinical development timelines and plans remains uncertain, and will depend on certain developments, including its impact on our clinical trial enrollment, trial sites, manufacturers, CROs and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. The ultimate impact of the COVID-19 pandemic, including the impact of new variants of the virus that causes COVID-19, or a similar health epidemic is highly uncertain and subject to change. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel and most of our non-lab-based employees working remotely. We will continue to actively monitor the evolving situation related to COVID-19 and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. At this point, the extent to which the COVID-19 pandemic may affect our business, operations and development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain and is subject to change.

### ***Financial operations overview***

Our combined 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 combined financial statements also include the accounts of our wholly-owned subsidiary HilleVax GmbH subsequent to its formation in May 2021. 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 combined companies; (ii) financing of each of the combined companies; (iii) control of board of directors of each of the combined companies; and (iv) management of each of the combined companies. All of the combined 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 combined financial statements report the financial position, results of operations and cash flows of the combined companies for all periods presented. All intercompany transactions have been eliminated in combination.

### ***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 500,000 shares of our common stock and a warrant to purchase 3,500,000 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 this offering, we will 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 this offering. We also paid Takeda \$2.5 million in cash upon the consummation of our convertible note financing in August 2021 and are obligated to pay an additional cash payment of \$2.5 million upon release of certain drug product 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 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. For additional information regarding the Takeda License, including termination provisions, see "Business—Intellectual property—License agreement with Takeda."

## **Components of results of operations**

### ***Operating expenses***

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

We did not incur any research and development expenses through December 31, 2020. Since December 31, 2020, our research and development expenses have 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.

## [Table of Contents](#)

We plan to substantially increase our research and development expenses for the foreseeable future as we continue the development of HIL-214. 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 or any future 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 future 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 the ongoing COVID-19 pandemic; and
- the safety, purity, potency, immunogenicity and efficacy of the vaccine candidate.

### ***In-process research and development***

In-process research and development expenses relate to the Takeda License, and includes the \$37.7 million purchase price of the acquired research and development assets. The purchase price of the Takeda License consisted of the following: (i) \$2.5 million in cash; (ii) issuance to Takeda of 500,000 shares of our common stock at a fair value of \$4.4 million; (iii) issuance of the Takeda Warrant at an initial fair value of \$30.5 million; (iv) issuance of the Takeda Warrant Right, with an initial fair value of \$34,000; and (v) \$0.3 million of transaction costs incurred by us. The fair value of the Takeda Warrant was derived from the model used to estimate the fair value of our common stock and the fair value of the common stock was determined using the methodologies described below under “Critical accounting policies and significant judgments and estimates—Common stock valuations.”

### ***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

## [Table of Contents](#)

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 expense***

Interest expense consists of interest on our outstanding convertible promissory notes.

### ***Change in fair value of warrant liabilities***

In connection with the Takeda License, we issued the Takeda Warrant and Takeda Warrant Right, or together the Takeda Warrants. The Takeda Warrants are accounted for as liabilities as they do not meet 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. We adjust the carrying value of our warrant liabilities 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 combined statements of operations.

Upon the closing of this offering, we expect the Takeda Warrants will be reclassified to stockholders' equity as a result of meeting the criteria for equity classification, and require a final adjustment to fair value.

### ***Change in fair value of convertible promissory notes***

We issued convertible promissory notes in 2019 and 2020 for which we have elected the fair value option. We adjust 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 combined statements of operations. All outstanding convertible promissory notes and related accrued interest will convert into shares of our common stock upon the closing of this offering.

The fair value of our convertible promissory notes has been 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.



## Results of operations

### Comparison of the nine months ended September 30, 2020 and 2021

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

	Nine Months Ended September 30,		Change
	2020	2021	
Operating expenses:			
Research and development	\$ —	\$ 1,623	\$ 1,623
In-process research and development	—	37,666	37,666
General and administrative	850	3,064	2,214
Total operating expenses	850	42,353	41,503
Loss from operations	(850)	(42,353)	(41,503)
Other income (expense):			
Interest expense	(21)	(734)	(713)
Change in fair value of convertible promissory notes	(513)	(1,392)	(879)
Change in fair value of warrant liabilities	—	(20,598)	(20,598)
Other income (expense)	—	(4)	(4)
Total other income (expense)	(534)	(22,728)	(22,194)
Net loss	<u>\$(1,384)</u>	<u>\$(65,081)</u>	<u>\$(63,697)</u>

*Research and development expenses.* We had no research and development expenses for the nine months ended September 30, 2020 as we had not yet identified or in-licensed a product candidate. The \$1.6 million of research and development expenses for the nine months ended September 30, 2021 consisted of \$0.6 million of consulting expenses, \$0.5 million of clinical development expenses for HIL-214 and \$0.5 million of personnel-related expenses.

*In-Process research and development expenses.* We had no in-process research and development expenses for the nine months ended September 30, 2020. The \$37.7 million of in-process research and development expenses for the nine months ended September 30, 2021 consisted of the purchase price for the research and development assets we acquired as part of the Takeda License.

*General and administrative expenses.* General and administrative expenses were \$0.9 million and \$3.1 million for the nine months ended September 30, 2020 and 2021, respectively. The increase of \$2.2 million was due to increases of \$0.7 million in legal fees related to corporate matters, \$0.8 million in professional services expenses for accounting, audit, tax, valuation and other services and \$0.7 million in personnel-related expenses.

*Other income (expense).* Other expense of \$0.5 million for the nine months ended September 30, 2020 consisted of \$21,000 of interest expense on our outstanding convertible promissory notes and \$0.5 million of other expense related to the increase in fair value of those convertible promissory notes. Other expense of \$22.7 million for the nine months ended September 30, 2021 consisted of \$20.6 million of other expense related to the increase in the fair value of warrant liabilities, \$1.4 million of other expense related to the increase in the fair value of our convertible promissory notes and \$0.7 million of interest expense on our outstanding convertible promissory notes.

**Comparison of the period from January 8, 2019 (inception) to December 31, 2019 and the year ended December 31, 2020**

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

	Period from January 8, 2019 (inception) to December 31, 2019	Year ended December 31, 2020	Change
Operating expenses:			
General and administrative	\$ 633	\$ 1,295	\$ 662
Total operating expenses	633	1,295	662
Loss from operations	(633)	(1,295)	(662)
Other income (expense):			
Interest expense	(9)	(29)	(20)
Change in fair value of convertible promissory notes	(31)	(779)	(748)
Total other income (expense)	(40)	(808)	(768)
Net loss	<u>\$ (673)</u>	<u>\$ (2,103)</u>	<u>\$ (1,430)</u>

**General and administrative expenses.** General and administrative expenses were \$0.6 million and \$1.3 million for the period from January 8, 2019 (inception) to December 31, 2019 and the year ended December 31, 2020, respectively. The increase of \$0.7 million was primarily due to increases in personnel-related expenses.

**Other income (expense).** Other expense of \$40,000 for the period from January 1, 2019 (inception) to December 31, 2019 consisted of \$9,000 of interest expense on our outstanding convertible promissory notes and \$31,000 of other expense related to the increase in fair value of such convertible promissory notes. Other expense of \$0.8 million for the year ended December 31, 2020 consisted of \$0.8 million of other expense related to the increase in the fair value of our convertible promissory notes and \$29,000 of interest expense on our outstanding convertible promissory notes.

**Unaudited pro forma net loss per share**

The unaudited pro forma basic and diluted net loss per share reflects (i) the automatic conversion of all outstanding convertible promissory notes and related accrued interest into \_\_\_\_\_ shares of common stock (assuming an IPO price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus and assuming the conversion occurs on \_\_\_\_\_ 2021, the expected closing date of this offering), and (ii) the reclassification of the Takeda Warrant to stockholders' equity (deficit), each as of the beginning of the period presented or the issuance date, if later.

The unaudited pro forma basic and diluted net loss per share amounts do not give effect to the issuance of common stock issued in this offering nor do they give effect to potential dilutive securities where the impact would be anti-dilutive.

## [Table of Contents](#)

The following table summarizes our unaudited pro forma net loss per share (in thousands, except share and per share data):

	Year Ended December 31, 2020	Nine Months Ended September 30, 2021
<b>Numerator</b>		
Net loss	\$ (2,103)	\$ (65,081)
Interest expense on convertible promissory notes	29	734
Change in fair value of Takeda Warrant	—	20,598
Change in fair value of convertible promissory notes	779	1,392
Pro forma net loss	<u>\$ (1,295)</u>	<u>\$ (42,357)</u>
<b>Denominator</b>		
Weighted-average shares of common stock outstanding, basic and diluted	2,598,266	3,156,879
Pro forma adjustments to reflect assumed weighted-average effect of conversion of convertible promissory notes		
Pro forma weighted-average shares of common stock outstanding, basic and diluted		
Pro forma net loss per share, basic and diluted	<u>\$</u>	<u>\$</u>

## 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. We have funded our operations to date through the issuance of convertible promissory notes. As of September 30, 2021, we had cash of \$129.6 million.

### **Convertible 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 bear interest at a rate of 6% per annum, compounded annually. The August 2021 Notes become payable upon demand of the holders of at least a majority of the outstanding principal, including Frazier (the Requisite Holders), on August 31, 2022 (the Maturity Date), and become due and payable on August 31, 2024, subject to earlier conversion or repayment in the event we complete certain equity financings or a change of control. The August 2021 Notes will automatically convert into shares of our common stock immediately prior to the completion of this offering.

### **Funding requirements**

Based on our current operating plan, we believe that our existing cash, together with the estimated net proceeds from this offering, will be sufficient to meet our anticipated cash requirements through at least the next months. In particular, we expect the net proceeds from this offering will allow us to complete . 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 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 future vaccine candidates;
- any delays and cost increases that may result from the COVID-19 pandemic;
- 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 future 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, debt financings, or other capital sources, including

## [Table of Contents](#)

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. We have prepared cash flow forecasts which indicate that based on our expected operating losses, negative cash flows and maturities of outstanding convertible promissory notes, there is substantial doubt about our ability to continue as a going concern without raising additional capital within 12 months after the date that the combined financial statements for the year ended December 31, 2020 and the nine months ended September 30, 2021 were issued. Our independent registered public accounting firm also included an explanatory paragraph in its report on our combined financial statements as of and for the year ended December 31, 2020 indicating that there is substantial doubt about our ability to continue as a going concern.

### **Cash flows**

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

	Period from January 8, 2019 (inception) to December 31, 2019	Year Ended December 31, 2020	Nine Months Ended September 30,	
			2020	2021
Net cash provided by (used in):				
Operating activities	\$ (474)	\$ (1,272)	\$ (959)	\$ (3,101)
Investing activities	—	—	—	(2,778)
Financing activities	877	1,326	1,026	135,001
Net increase in cash	<u>\$ 403</u>	<u>\$ 54</u>	<u>\$ 67</u>	<u>\$ 129,122</u>

### **Operating activities**

Net cash used in operating activities was approximately \$0.5 million for the period from January 8, 2019 (inception) to December 31, 2019 and \$1.3 million for the year ended December 31, 2020. The net cash used in operating activities for the period from January 8, 2019 (inception) to December 31, 2019 and the year ended December 31, 2020 was primarily due to our net loss in each period, adjusted for net changes in operating assets and liabilities and noncash charges related to our outstanding convertible promissory notes. Net cash used in operating activities for the nine months ended September 30, 2020 of \$1.0 million was due to our net loss of \$1.4 million, adjusted for \$0.5 million of noncash charges and a \$0.1 million net change in operating assets and liabilities. Net cash used in operating activities for the nine months ended September 30, 2021 of \$3.1 million was due to our net loss of \$65.1 million, adjusted for \$59.7 million of noncash charges and a

## [Table of Contents](#)

\$2.3 million net change in operating assets and liabilities. Noncash charges consisted of our in-process research and development charges of \$37.7 million related to the Takeda License, \$1.4 million related to the change in fair value of convertible promissory notes and \$20.6 million related to the change in fair value of warrant liabilities. The net change in operating assets and liabilities primarily related to a \$0.7 million increase in accrued interest on our outstanding convertible promissory notes and a \$1.6 million increase in accounts payable and accrued expenses in support of the growth in our operating activities.

### **Investing activities**

Net cash used in investing activities for the nine months ended September 30, 2021 was primarily due to the cash we paid, including transaction costs, to acquire the Takeda License and payments for the acquisition of property and equipment. We had no investing activities prior to 2021.

### **Financing activities**

Net cash provided by financing activities for the period from January 8, 2019 (inception) to December 31, 2019, the year ended December 31, 2020 and the nine months ended September 30, 2020 and 2021 was primarily due to proceeds from our issuance of convertible promissory notes.

## **Contractual obligations and commitments**

The following table summarizes our contractual obligations as of December 31, 2020 (in thousands):

	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>Less than 1 Year</b>	<b>1—3 Years</b>	<b>3—5 Years</b>	<b>More than 5 Years</b>
Convertible promissory notes(1)(2)	\$2,214	\$ 2,214	\$ —	\$ —	\$ —
Total(3)	<u>\$2,214</u>	<u>\$ 2,214</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

(1) As of December 31, 2020, our outstanding convertible promissory notes were scheduled to mature at various dates through October 2021. The amounts exclude interest since such amounts are not material.

(2) The table above excludes the issuance of \$6.3 million of convertible promissory notes issued between April and July 2021 and the subsequent conversion of all then outstanding convertible promissory notes into the August 2021 Notes described above. The current outstanding principal balance of the August 2021 Notes is \$139.5 million.

(3) The table above excludes future minimum noncancelable operating lease payments of approximately \$0.2 million under a September 2021 lease 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 and, therefore, any related payments are not included in the table above.

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 and not included in the table above.

## **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 combined financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States (GAAP). The preparation of our combined 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 combined 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 1 to our combined financial statements included elsewhere in this prospectus, 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 combined 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 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, our warrant liabilities and convertible promissory notes are revalued at each reporting period with changes in the fair value of the liabilities recorded as a component of other income (expense) in the combined statements of operations. See Note 1 to our combined financial statements included elsewhere in this prospectus 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 recognized over the requisite service period of the awards (generally the vesting period) on a straight-line basis with forfeitures recognized as they occur. Since all equity awards from inception to September 30, 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 as of September 30, 2021.

### ***Common stock valuations***

Prior to obtaining the Takeda License in July 2021, the fair value of our common stock was nominal because we were not sufficiently capitalized and held no assets that could be used to generate future revenues. Subsequent to obtaining the Takeda License, we estimated the fair value of our common stock using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide: *Valuation of Privately Held Company Equity Securities Issued as Compensation*, or the Practice Aid. The Practice Aid prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. We utilized a scenario-based analysis that estimated the fair value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, including various initial public offering, stay private and dissolution scenarios, and applying a discount for lack of marketability for certain equity holders. We considered various stay private scenarios using the income approach and allocated the indicated equity value, adjusted for the expected impact of the convertible notes, to each class of equity on a fully-diluted basis, considering option value for certain option classes. We also considered various initial public offering scenarios based on expected equity values in an initial public offering and allocated the indicated equity value to each class of equity on a fully-diluted basis considering the dilutive impacts of the convertible notes.

We considered various objective and subjective factors to determine the fair value of our common stock, including:

- valuations of our common stock performed with the assistance of independent third-party valuation specialists;
- our stage of development and business strategy, including the status of research and development efforts of HIL-214, and the material risks related to our business and industry;
- our results of operations and financial position, including our levels of available capital resources;
- the valuation of publicly-traded companies in the life sciences and biotechnology sectors;
- the lack of marketability of our common stock as a private company for certain equity holders;

## [Table of Contents](#)

- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering or a sale of our company, given prevailing market conditions;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and biotechnology industry sectors.

There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates include assumptions regarding our future operating performance, the time to complete an initial public offering or other liquidity event and the determination of the appropriate valuation methods. If we had made different assumptions, our net loss and net loss per common share could have been significantly different.

Following the completion of this offering, the fair value of our common stock will be based on the closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded.

### **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 combined 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 this offering, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.07 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 1 to our combined financial statements appearing elsewhere in this prospectus for recent accounting pronouncements.

## **Off-balance sheet arrangements**

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

## **Quantitative and qualitative disclosures about market risk**

### ***Interest rate risk***

Our cash consists of cash in readily available checking accounts. As a result, the fair value of our portfolio is relatively insensitive to interest rate changes. Our outstanding convertible promissory notes bear interest at a fixed rate and therefore have no exposure to changes in interest rates.

### ***Effects of inflation***

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

## 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 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 Vaccines, Inc. (Takeda) and its predecessor, LigoCyte Pharmaceuticals, Inc. (LigoCyte), which collectively generated safety data from more than 4,500 subjects and immunogenicity, or the ability of the vaccine to provoke an immune response, data from more than 2,200 subjects. These trials also generated 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 plan to initiate a Phase 2b clinical trial in to evaluate the safety, immunogenicity, and efficacy of HIL-214 in infants. We expect to report safety and immunogenicity data from this trial for the first 200 subjects in and top-line data in . 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.

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. Up to 80% of children will experience a norovirus infection within one year of birth, with the majority of cases occurring between six months and two years of age. 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 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 November 15, 2021, our intellectual property portfolio for HIL-214 includes six issued U.S. composition and formulation patents that 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, drowsiness, diarrhea, and pain near the injection site. 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. 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).

## [Table of Contents](#)

Our near-term clinical development plan is focused on infants, a population in which norovirus is routinely circulating and infections are common. We plan to initiate a Phase 2b clinical trial in \_\_\_\_\_ to evaluate the safety, immunogenicity, and efficacy of HIL-214 in infants. We expect to report a safety and immunogenicity analysis from this trial for the first 200 subjects in \_\_\_\_\_ and top-line data in \_\_\_\_\_. While Takeda previously conducted both Phase 2 and 2 clinical trials of HIL-214, we have not previously completed any clinical trials. After conclusion of the Phase 2b trial in infants, we plan to proceed to a pivotal Phase 3 efficacy trial in infants. 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 nearly universally 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 is estimated to be over \$50 billion in 2020 and is expected to exceed \$100 billion by 2027. 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 2020. In the older adult market, we believe that Shingrix, a vaccine developed by GlaxoSmithKline to prevent shingles, is an analogue for HIL-214 due to the similarities in morbidity, mortality and economic burden between shingles and norovirus each before the introduction of a vaccine. Shingrix generated \$2.7 billion in sales in 2020. 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 company was founded by Frazier and Takeda Pharmaceuticals with the goal of developing and commercializing the first vaccine for norovirus-related illness. Our late co-founder, Tachi Yamada, M.D., was the former Chief Medical and Scientific Officer at Takeda Pharmaceuticals. Since our founding, we have assembled a distinguished group of executives, directors, and advisors with extensive experience in vaccine development, clinical trial operations, manufacturing, and commercialization, including prior experience developing HIL-214 at Takeda Pharmaceuticals. Our President, Chief Executive Officer, and Chairman, Rob Hershberg, M.D., Ph.D., was previously Executive Vice President and Chief Scientific Officer of Celgene and was subsequently Executive Vice President and Head of Business Development & Global Alliances and served as a member of the Executive Committee until the acquisition of Celgene by Bristol-Myers Squibb in 2019. David Socks, our Chief Financial Officer and Chief Business Officer, co-founded Arcutis, Cadence Pharmaceuticals, Incline Therapeutics, Passage Bio, and Phathom Pharmaceuticals, where he was the Chief Executive Officer through the company's initial public offering in 2019 and later served as interim Chief Financial Officer. Aditya Kohli, Ph.D., our Chief Operating Officer, co-founded Scout Bio, Passage Bio, and Phathom Pharmaceuticals and currently serves as the Chief Business Officer at Phathom and on the board of Scout Bio. Astrid Borkowski, M.D., Ph.D., our Chief Medical Officer, is the former VP, Head of Clinical Development at Takeda Pharmaceuticals' Vaccine Business Unit where she oversaw the clinical development of all vaccine assets, including HIL-214. Paul Bavier, our General Counsel, Secretary, and Chief Administrative Officer, is the former General Counsel at VelosBio, Avedro and Bidel.

## Table of Contents

Since our inception, we have raised over \$135 million in capital from leading investors, including Frazier Healthcare Partners, RA Capital Management, Deerfield Management Company, Abingworth, Lightspeed Venture Partners, Perceptive Advisors, Franklin Templeton, Catalys Pacific, Samsara BioCapital, BVF Partners LP, Qiming Venture Partners USA, Greenspring Associates, Richard King Mellon Foundation, and Sahsen Ventures.

## Our pipeline

The following chart summarizes our current development programs.

Program <sup>1</sup>	Description	Disease	Target population	Age	Phase 1	Phase 2	Phase 3	Anticipated milestones
HIL-214	GI.1 / GI.4 VLP-based vaccine	Norovirus-related illness	Infants <sup>2</sup>	5 months				Phase 2b trial initiation ( 2022)
			Children <sup>2,3</sup>	2 – 9 years				Immunobridging and/or efficacy studies after Phase 2b trial in infants
			Adults <sup>2,4</sup>	18 – 59 years				
			Older adults <sup>2</sup>	≥ 60 years				

1. All trials to date conducted by Takeda and Ligocyte. See page 5 for a table showing the completed clinical trials for HIL-214.

2. Completed Phase 2 trial(s) evaluating 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.

## 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 plan to initiate a Phase 2b clinical trial in [redacted] to evaluate the safety, immunogenicity, and efficacy of HIL-214 in infants. We expect to report interim safety and immunogenicity data from this trial for the first 200 subjects in [redacted] and top-line data in [redacted]. Pending the successful completion of the planned Phase 2b 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 [redacted]



the United States, we plan to seek one or more partners with existing commercial infrastructure and expertise in these markets.

- **Pursue expansion strategies for HIL-214.** We plan to support alternative formulations or combinations where there is clear unmet need, clinical rationale, and commercial justification. We also plan to further expand the breadth of coverage for our norovirus vaccine through the addition of new norovirus strains to cover relevant or emerging genotypes as needed.
- **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.

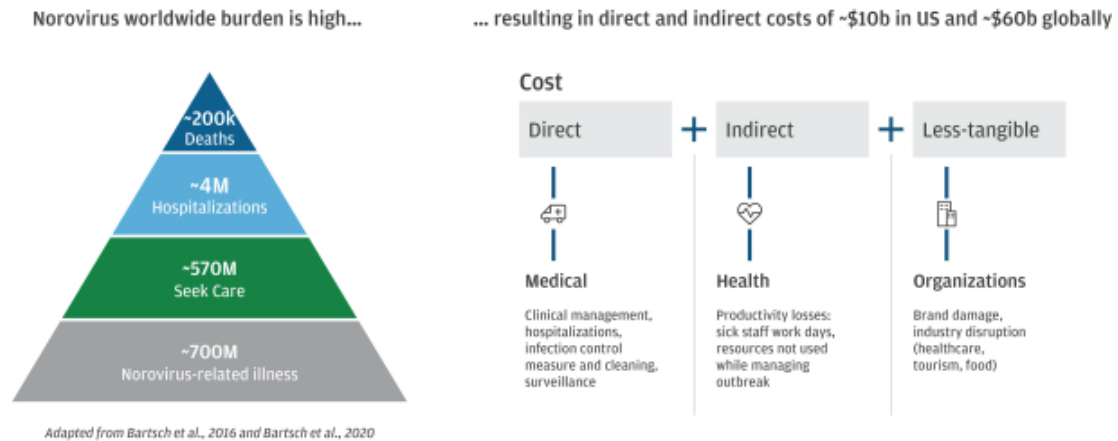
## Overview of norovirus

### *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.

## Table of Contents

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.

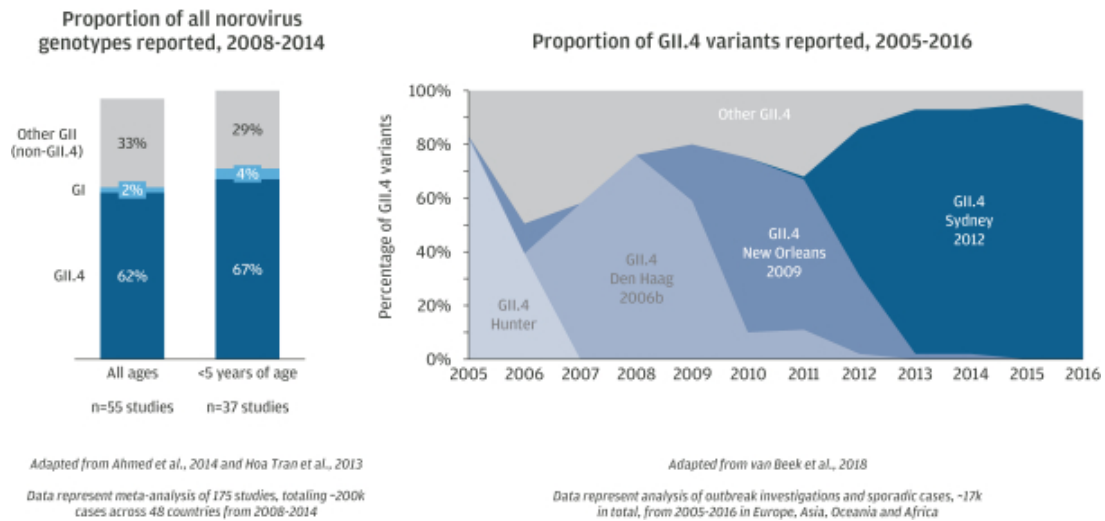


## Genogroups and genotypes

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.

## Table of Contents

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.

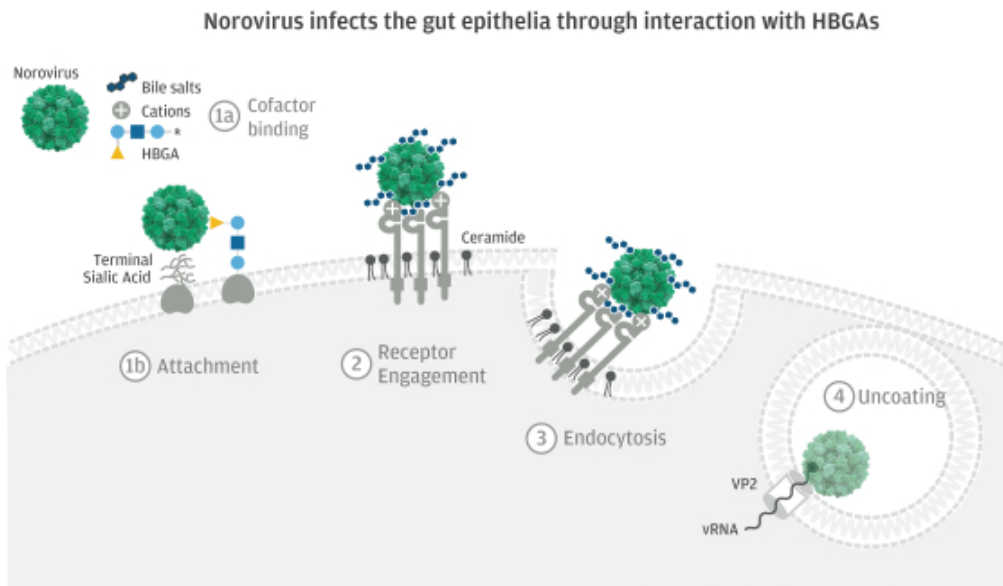


## Norovirus attachment and entry

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 into body fluids, 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 planned clinical trials of HIL-214 will help determine whether anti-HBGA antibodies are an appropriate surrogate for evaluating norovirus vaccine efficacy.

## [Table of Contents](#)

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  $R_0$  (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  $R_0$  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. Food 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. Up to 80% of children will experience a norovirus infection within one year of birth, with the majority of cases occurring between six months and two years of age. 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

## [Table of Contents](#)

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 and shingles burden (pre-vaccines) in the United States

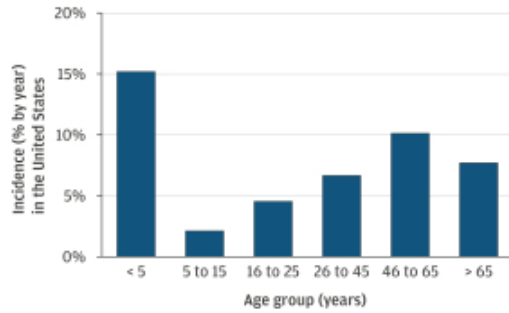
Disease	Age	US cases	US hospitalizations	US deaths	US economic burden <sup>1</sup>
Norovirus	≤ 4 years	2.8 million	12,000	20	\$1.2 billion
	5 - 64 years	15.7 million	34,000	70	\$6.4 billion
	≥ 65 years	3.7 million	50,000	1,250	\$3.2 billion
	All ages	22 million	96,000	1,350	\$10 billion
Rotavirus (pre-vaccine)	≤ 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

1. Adjusted to 2020 dollars  
Adapted from CDC, Bartsch et al., 2020, Harvey et al., 2019, Insinga et al., 2007

### **Burden in older adults**

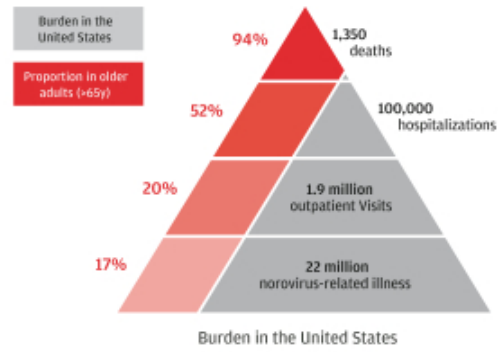
Adults older than 65 are another high-risk group for norovirus infections. In the United States, older adults are estimated to account for 17% of illnesses due to norovirus yet comprise 52% of hospitalizations and 94% of deaths. Symptoms are often more severe in this age group and include diarrhea lasting 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.

**Norovirus incidence is highest in children under 5...**



Adapted from Grytdal et al., 2016. Represents community incidence of norovirus AGE among outpatients in Kaiser Permanente health plans in the United States, 2012-2013

**... but morbidity and mortality is highest in older adults**



Adapted from Bartsch et al., 2020

**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 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.

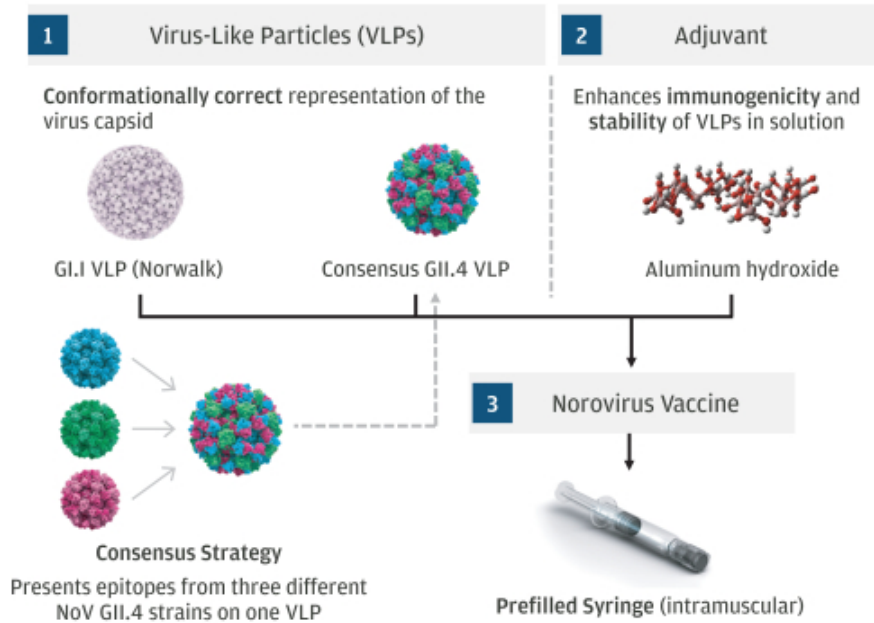
There is ample precedent for the development of safe and effective vaccines that leverage VLP technology. Gardasil, a commercially available vaccine for human papillomavirus (HPV) developed by Merck, consists of recombinant VLPs self-assembled from the capsid protein of HPV types 6, 11, 16, and 18. A 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 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 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 design contains VLPs for major genotypes GI.1 and GII.4**



## HIL-214 clinical data

### Overview

HIL-214 has been the subject of nine Phase 1 and Phase 2 clinical trials, 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	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/> <i>Challenge</i>	18 – 50 yrs	N/A <sup>1</sup>	N/A <sup>1</sup>	
	LV03-104	1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		18 – 85 yrs	66	66	
	LV03-105	1/2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/> <i>Challenge</i>	18 – 50 yrs	67	67	
Takeda	NOR-210	2	<i>Generation of serum controls for assay validation</i>					18 – 49 yrs	50	50
	NOR-107	2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			18 – 64 yrs	418	418	
	NOR-201	2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			18 – 49 yrs	425	425	
	NOR-204	2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		18 – >85 yrs	311	311	
	NOR-211	2b	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/> <i>Field study</i>	18 – 49 yrs	2,355	97	
	NOR-202	2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		6 wks – 9 yrs	839	839	
							<b>TOTAL:</b>	<b>4,531</b>	<b>2,273</b>	

<sup>1</sup>. Intranasal formulation of vaccine, not included in HIL-214 safety and immunogenicity subject numbers

### Dose finding and formulation trials in infants and children

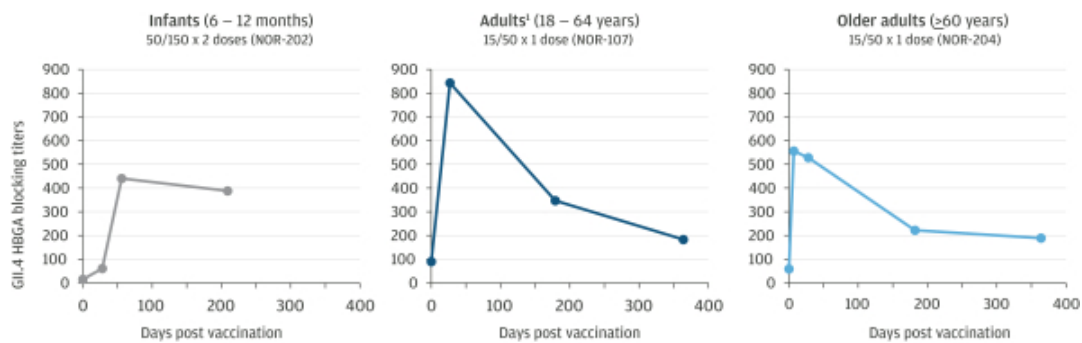
A Phase 2 dose finding and formulation trial has been conducted in infants and children for HIL-214. Based on the results from this trial, in addition to considerations around disease burden and maternal antibody concentrations, we have selected the following dose and schedule to continue to evaluate 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 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 injection site pain and tenderness, 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.

**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 (without a placebo control). 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. 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 mild injection site pain, headache, and fatigue, 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.

**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 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 muscle pain, headache, and fatigue, 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.

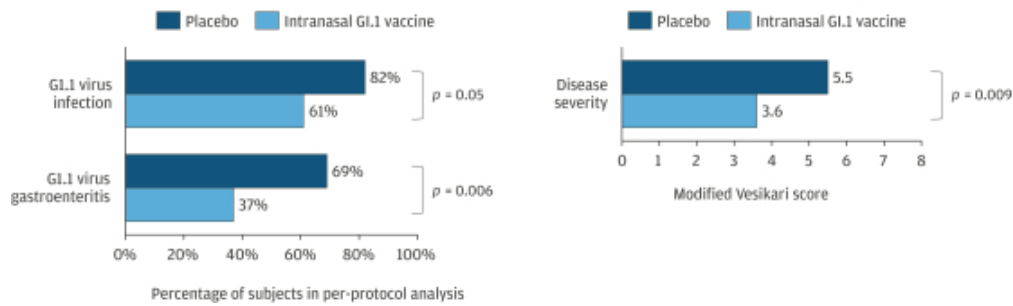
**NOR-204**—A Phase 2, randomized, double-blind trial to evaluate the safety, immunogenicity, dose formulation, and dose regimen of HIL-214 in 320 healthy adults aged 18 to over 85 years old (without a placebo control). Older adults were stratified into three groups of 60-74 years, 75-84 years and greater 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. The most common AEs were injection site pain, fatigue, and muscle pain, 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.

### ***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. The vaccine formulation used in the trial contained 100 µg of GI.1 VLP and was adjuvanted with chitosan and MPL. Subjects were between 18 and 50 years of age and received two doses of either 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,  $p = 0.009$ ).

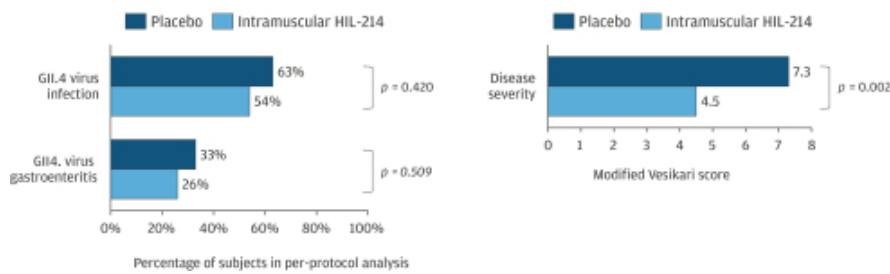
**Vaccination with intranasal GI.1 VLP protected against subsequent norovirus challenge (LV01-103)**



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 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.

**Vaccination with intramuscular HIL-214 reduced disease severity in subsequent norovirus challenge (LV03-105)**



**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 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		AGE severity	
Pathogen		Placebo N = 2,357	HIL-214 N = 2,355	%	p value	Placebo N = 2,357	HIL-214 N = 2,355
1 <sup>o</sup>	HIL-214 vaccine strain only <sup>1</sup>	5	1	80.0	$p = 0.142$	Moderate	10
2 <sup>o</sup>	Any norovirus strain	26	10	61.8	$p = 0.0097$	Severe	17
Post-hoc	GII.2 strain	21	9	57.4	$p = 0.0321$		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 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%). 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 vaccine design, disease under evaluation, trial designs and subject characteristics.

Pediatric safety summary for HIL-214

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



## Table of Contents

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 vaccine design, disease under evaluation, trial designs, and subject characteristics.

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 <sup>4</sup>	48%	6%	35%	
		>60 years <sup>5</sup>	33%	<1%	8%	
COVID-19	Comirnaty	16 to 55 years	78 - 84% <sup>1</sup>	4 - 16% <sup>3</sup>	44 - 54% <sup>3</sup>	
	Moderna	18 to 64 years	87 - 90% <sup>1</sup>	1 - 17% <sup>3</sup>	35 - 63% <sup>1</sup>	
HPV	Gardasil 9	16 to 26 years	71 - 74% <sup>2</sup>	2 - 3% <sup>2</sup>	15%	
Influenza	Afluria	18 to 64 years	48%	1%	22%	
	FluBlok	>50 years	19%	<1%	13%	
Shingles	Shingrix	>50 years	69 - 88% <sup>3</sup>	14 - 28% <sup>3</sup>	29 - 51% <sup>3</sup>	

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

We plan to build on the extensive clinical data generated to date by initiating our next 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.

This clinical trial will be a Phase 2b, randomized, double-blind, placebo-controlled trial to evaluate the efficacy, safety, and immunogenicity of HIL-214 in infants of approximately 5 months of age at time of initial vaccination at sites in the United States and Latin America. We believe 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. We plan to enroll 3,000 subjects (irrespective of *FUT2* secretor status) who will be randomized 1:1 to receive either HIL-214 or placebo. In the vaccine arm, subjects will receive 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 will receive saline placebo at the corresponding timepoints. The dosage and scheduling were based on learnings from the NOR-202 Phase 2 trial. We expect that the primary objective of the trial will be to evaluate the protective efficacy of HIL-214 against the first confirmed moderate or severe AGE event due to GI.1 or GII.4 norovirus strains (excluding certain co-infections) that occurs prior to each subject reaching 12 months of age. Key secondary endpoints may include evaluation of the protective efficacy of HIL-214 against any GI or GII norovirus strain. We plan to conduct a pre-specified safety and immunogenicity analysis on the first 200 subjects.

### NOR-212 (Phase 2b efficacy study in infants)



We are developing and 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 our planned Phase 2b clinical trial based on learnings from the NOR-211 Phase 2b study and the NOR-202 Phase 2 study, as well as preliminary feedback Takeda received from the FDA and European Medicines Agency (EMA). We expect to report safety and immunogenicity data for the first 200 subjects in [redacted] and top-line results from this Phase 2b trial in [redacted].

### Phase 3 infant efficacy trial

Based on the results from our planned Phase 2b trial, if positive, we plan to interact 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 5,000 to 6,000 subjects that will be randomized 1:1 into the vaccine or control arm. Trial sites under consideration include those located in the United States, Latin America, Europe, and Japan.

### NOR-335 (Phase 3 efficacy study in infants)



### ***Other trials in infants***

We are planning additional trials in infants to support regulatory submissions and the potential co-administration of HIL-214 with common pediatric vaccines. These potentially include a Phase 3 trial to evaluate the safety and immunogenicity of HIL-214 when co-administered with other routine pediatric vaccines and 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 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 \$50 billion in 2020 and is expected to exceed \$100 billion by 2027. Pneumococcal vaccines have historically been the largest vaccine category, with \$7.0 billion in sales in 2020. COVID-19 vaccines are expected to become the largest category in 2021. 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 \$1.6 billion in sales in 2020. 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, is an analogue for HIL-214 due to the similarities in morbidity, mortality and economic burden between shingles and norovirus each before the introduction of a vaccine. Shingrix generated \$2.7 billion in sales in 2020. 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.

## **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

## [Table of Contents](#)

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 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 plan to use clinical material that was previously manufactured by Takeda. We plan to continue to use third-party manufacturers to produce cGMP material 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 November 15, 2021, 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 8 distinct patent families protecting the technology relating to HIL-214 composition of matter, methods of

## [Table of Contents](#)

manufacturing HIL-214, formulations of HIL-214 products, as well as methods of use of HIL-214. As of November 15, 2021, our portfolio consists of approximately 22 issued U.S. patents, 5 pending U.S. patent applications, 62 issued foreign patents including 6 issued European patents subsequently validated in individual European countries, and 54 foreign patent applications pending in major international markets. The issued patents and pending applications have nominal expiration dates ranging from 2027 to 2039, without accounting for any available patent term adjustments or extensions.

More specifically, 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 granted patents in Australia, Canada, Hong Kong, Europe, Republic of Korea and Singapore 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 granted patents in Australia, Europe, Hong Kong, Lebanon, Republic of Korea, Mexico and Taiwan, 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 applications in Argentina, Bangladesh, Canada, China, Gulf Co-Operation Council, India, Iran, Jordan, Pakistan, Singapore, Uruguay, 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 in-licensed six patent families covering VLP compositions and methods of use. One of these families contains seven U.S. patents, all projected to expire in 2027, as well as granted patents in Australia, Canada, Europe, Hong Kong, 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 four U.S. patents projected to expire from 2027 to 2028, as well as granted patents in Australia, Canada, China, 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 are additional pending applications in the U.S. and 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 granted patents in Australia, Canada, China, Macau, Europe, Hong Kong, Republic of Korea 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 are additional pending applications in China, Europe and Hong Kong, all projected to expire in 2029, in each case without accounting for any available patent term adjustments or extensions.

## [Table of Contents](#)

A fourth family covering VLP compositions and methods of use contains two US patents projected to expire in 2032, as well as granted patents in Australia, Chile, Eurasia, Europe, Georgia, Hong Kong, Israel, India, Republic of Korea, Morocco, Mexico, Malaysia, New Zealand, Peru, Philippines, Tunisia, Ukraine, Vietnam and South Africa, also projected to expire in 2032, in each case without accounting for any available patent term adjustments or extensions. The European patent in this family was Switzerland, Germany, Spain, France, the United Kingdom, Italy, Netherlands, Poland and Sweden. There are additional pending applications in Algeria, Brazil, Canada, China, Costa Rica, Dominican Republic, Ecuador, Egypt, Europe, Eurasia, Hong Kong, Indonesia, Philippines, Singapore, Thailand, United States 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 are pending applications in Argentina, Australia, Brazil, Canada, China, Colombia, Europe, 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. There is an additional pending application in Europe, projected to expire in 2039.

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 500,000 shares of common stock and a warrant to purchase 3,500,000 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 this offering, we will 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 this offering (the Takeda Warrant Right). We also paid Takeda a cash payment of \$2.5 million upon the consummation of our convertible note financing in August 2021 and are obligated to pay an additional cash payment of \$2.5 million upon release of certain drug product 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.

## **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,

## [Table of Contents](#)

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 investigational new drug application (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. 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](http://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.

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.

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.

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. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

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 will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

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. Once a BLA is approved, the FDA may withdraw such approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may 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 candidate 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 and accelerated approval. 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, 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. 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. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured are still being worked out by the FDA.

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 other exclusivity protection or patent term, 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, data privacy and security, 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 European Union (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 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. The U.S. Supreme Court is currently reviewing the constitutionality of the ACA in its. Although the Supreme Court has not yet ruled, 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 Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, 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. The likelihood of success of these and other reforms initiated by the former Trump administration is unclear, particularly in light of the new Biden administration.

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.

### ***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 and any commercial sales and distribution of our product candidates. 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. 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 studies must be conducted in compliance with the principles of good laboratory practice (GLP) as set forth in EU Directive 2004/10/EC. 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 Conference on Harmonization (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 countries, 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 much like the IND prior to the commencement of human clinical studies. A CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved by the national health authority and the ethics committee has granted a positive opinion in relation to the conduct of the trial in the relevant member state(s), in accordance with a country's requirements, clinical study development may proceed.

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. Currently, CTAs must be submitted to the competent authority in each EU member state in which the trial will be conducted. Under the new Regulation on Clinical Trials, which is currently expected to become applicable by early 2022, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only limited involvement. Any substantial changes to the trial protocol or other information submitted with the CTA must be notified to or approved by the relevant competent authorities and ethics committees. 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 the EU, medicinal products 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 marketing authorization application (MAA). The application used to file the BLA in the United States is similar to that required in the EU, with the exception of, among other things, country specific document requirements. The process for doing this depends, among other things, on the nature of the medicinal product.

The centralized procedure results in a single MA, issued by the European Commission, based on the opinion of the European Medicines Agency's (EMA) Committee for Human Medicinal Products (CHMP) which is valid across the entire territory of 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) 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, which are issued by the competent authorities of the EU member states and only cover their respective territory, 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. 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 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 the appointment of a CHMP rapporteur before submission of a MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application

process. Innovative medicines fulfilling a medical need may also benefit from different types of fast track approvals, such as a conditional MA or a MA under exceptional circumstances granted on the basis of less comprehensive clinical data than normally required (respectively in the likelihood that the sponsor will provide such data within an agreed timeframe or when comprehensive data cannot be obtained even after authorization).

Classical 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 chemical entities 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 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 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 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.

### ***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 who is responsible for oversight of that system. 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

## [Table of Contents](#)

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.

### ***Privacy and data protection laws***

We are also subject to laws and regulations in non-U.S. countries covering privacy and data security the protection of health-related and other personal information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. Laws and regulations in these jurisdictions apply broadly to the collection, use, storage, disclosure, transfer, security and other processing of personal information that identifies or may be used to identify an individual, such as names, contact information, and sensitive personal data such as health data. These laws and regulations are subject to frequent revisions and differing interpretations, and have generally become more stringent over time.

As of May 25, 2018, Regulation 2016/676, known as the General Data Protection Regulation (GDPR) replaced the Data Protection Directive with respect to the processing of personal data of individuals within the EEA. The GDPR imposes many requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data (including data from clinical trials) and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR is directly applicable in each member state and is extended to the EEA. However, the GDPR allows EEA countries to make additional laws and regulations further limiting, among other things, the processing of genetic, biometric or health data. Failure to comply with the requirements of the GDPR may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the U.S., and the efficacy and longevity of current transfer mechanisms between the EU and the U.S. remains uncertain. For example, in 2016, the EU and U.S. agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union (CJEU). While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal

regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain.

## **Legal proceedings**

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material proceedings. Regardless of 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.

## **Facilities**

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

## **Employees**

As of November 15, 2021, we had 15 full-time employees and no part-time employees. Of these employees, 7 hold Ph.D. or M.D. degrees and 9 are engaged in research and development. Our employees are not represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

## Management

### Executive officers and directors

The following table sets forth the name, age and position of each of our executive officers and directors as of November 15, 2021.

Name	Age	Position
<b>Executive Officers</b>		
Rob Hershberg, M.D., Ph.D.	58	Chairman, President and Chief Executive Officer
Aditya Kohli, Ph.D.	33	Chief Operating Officer
David Socks	47	Chief Financial Officer and Chief Business Officer
Astrid Borkowski, M.D., Ph.D.	52	Chief Medical Officer
<b>Non-Employee Directors</b>		
Shelley Chu, M.D., Ph.D.(4)	52	Director
Julie Gerberding, M.D. M.P.H.	66	Director
Patrick Heron	51	Director
Jeri Hilleman	64	Director
Jaime Sepulveda, M.D., D.Sc., M.P.H.	67	Director
Susan Silbermann	59	Director
Rajeev Venkayya, M.D.	54	Director
Elise Wang(4)	62	Director

(1) Member of the compensation committee

(2) Member of the audit committee

(3) Member of the nominating and corporate governance committee

(4) Dr. Chu and Ms. Wang will resign from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

### Executive officers

*Robert M. Hershberg, M.D., Ph.D.* is our co-founder and has served as our President and Chief Executive Officer and on our board of directors since March 2020. Since March 2020, Dr. Hershberg has been a Venture Partner at Frazier Healthcare Partners, a venture capital firm focused exclusively on biotechnology investments. From March 2017 until the acquisition of Celgene by Bristol-Myers Squibb in November 2019, Dr. Hershberg served as Executive Vice President of Business Development and Global Alliances of Celgene Corporation, a publicly traded biopharmaceutical company, where he was a member of the Executive Committee and was responsible for all business development related activities across the company and management of business alliances. From January 2016 to March 2017, Dr. Hershberg served as the Chief Scientific Officer, where he was responsible for overseeing Celgene's scientific platforms, discovery capabilities and early clinical development, and from July 2014 to January 2016, he served as Senior Vice-President of Immuno-Oncology at Celgene, where



he led Celgene's research and early development efforts across its immuno-oncology portfolio. From 2011 to 2017, Dr. Hershberg was President and Chief Executive Officer of VentiRx Pharmaceuticals, a clinical stage biopharmaceutical company, which he co-founded in 2006; from 2006 to 2011 he also served as its Executive Vice President and Chief Medical Officer. Prior to co-founding VentiRx, Dr. Hershberg served as Senior Vice President and Chief Medical Officer at Dendreon Corporation, a biotechnology company, where he led the clinical, regulatory and biometrics groups, focusing on the development of Provenge® in metastatic prostate cancer. From 2001 to 2003, Dr. Hershberg was the Vice President of Medical Genetics at Corixa, a pharmaceutical company (acquired by GlaxoSmithKline in 2005). Earlier in his career, Dr. Hershberg served as an Assistant Professor at Harvard Medical School and an Associate Physician at the Brigham and Women's Hospital in Boston, Massachusetts. Dr. Hershberg holds a clinical faculty position at the University of Washington School of Medicine and is a member of the scientific advisory board of the Institute for Protein Design at the University of Washington. He has served as an independent member of the board of directors of Adaptive Biotechnologies Corporation since February 2013, Fate Therapeutics, Inc. since April 2019, NanoString Technologies, Inc. since March 2015, Recursion Pharmaceuticals since June 2019, and Silverback Therapeutics since April 2017. He holds a B.S. in Molecular Biology and M.D. from UCLA, and a Ph.D. in Biology from the Salk Institute. We believe Dr. Hershberg's extensive experience as a senior executive officer at multiple biotechnology companies contributed to our board of directors' conclusion that he should serve as a director of our company.

*Aditya Kohli, Ph.D.* is our co-founder and has served as our Chief Operating Officer since February 2021. Since March 2019, Dr. Kohli has served as the Chief Business Officer of Phathom Pharmaceuticals, Inc. Since January 2021, Dr. Kohli has served as Venture Partner of Frazier Healthcare Partners. From January 2020 to December 2020, Dr. Kohli served as Principal of Frazier Healthcare Partners. From January 2018 to December 2019, Dr. Kohli served as Vice President of Frazier Healthcare Partners. From September 2016 to December 2017, Dr. Kohli served as Senior Associate of Frazier Healthcare Partners. In this capacity, he has co-founded HilleVax, Phathom Pharmaceuticals, Passage Bio, Scout Bio and Recida Therapeutics, Inc. and has served on the board of directors of Scout Bio since April 2019. Prior to joining Frazier Healthcare Partners, Dr. Kohli worked at McKinsey & Company as an Engagement Manager from June 2016 until September 2016 and as an Associate from September 2014 until May 2016, where he consulted with biopharmaceutical companies on business development, research and development, and marketing and sales strategy. Dr. Kohli received his Ph.D. from the UC Berkeley and UC San Francisco joint graduate program in bioengineering and holds B.S. and M.Eng. degrees in biological engineering from the Massachusetts Institute of Technology.

*David Socks* is our co-founder and has served as our Chief Financial Officer and Chief Business Officer since February 2021. Mr. Socks is also a co-founder and has served as a member of the board of directors of Phathom Pharmaceuticals, Inc. since January 2018. Mr. Socks previously served as the Chief Executive Officer of Phathom Pharmaceuticals from January 2018 until his appointment as interim Chief Financial Officer, a position he held from December 2019 until July 2020. Since July 2020, Mr. Socks has served as a Strategic Advisor to Phathom Pharmaceuticals. Since July 2021, he has served as Chairman of the board of directors of Eleusis Holdings Limited. From August 2014 to September 2021, Mr. Socks was a Venture Partner at Frazier Healthcare Partners. In this capacity, he co-founded Arcutis, Inc., Passage Bio, and multiple private companies for which he served as Chief Executive Officer. Prior to joining Frazier, Mr. Socks co-founded Incline Therapeutics, Inc. in 2010 and served as its President and Chief Operating Officer from 2010 until its sale to The Medicines Company in 2013. He also co-founded Cadence Pharmaceuticals, Inc. in 2004 and served as its Vice President of Business Development and then as its Senior Vice President, Corporate Development and Strategy from 2004 until 2010. From 2000 to 2004, Mr. Socks was a Venture Partner at Windamere Venture Partners, a venture capital firm founding and investing in early stage life science companies, where he cofounded multiple biopharmaceutical companies. Mr. Socks holds a B.S. from Georgetown University and an M.B.A. from Stanford University.

## [Table of Contents](#)

*Astrid Borkowski, M.D., Ph.D.* has served as our Chief Medical Officer since March 2021. Prior to HilleVax, Dr. Borkowski served as Vice President, Head of Clinical Development at Takeda Pharmaceuticals' Vaccine Business Unit, where she oversaw the clinical development of vaccine assets, including HIL-214, from October 2012 to April 2021. Prior to joining Takeda Pharmaceuticals, Dr. Borkowski was Chief Medical Officer responsible for the European Region and later led early viral and bacterial vaccine development at Novartis Vaccines from January 2007 to September 2012. Prior to Novartis, she served as Director, Worldwide Clinical Development Influenza Vaccines from January 2006 to December 2006 at GSK, where she was responsible for the pandemic influenza vaccine development. From 2000 to 2005, Dr. Borkowski served as Global Clinical Team Leader CR&MA at Chiron Vaccines where she worked on meningococcal and seasonal influenza vaccine development. Dr. Borkowski completed her Medical Degree at the Humboldt University in Berlin, Germany, from which she also received her Ph.D. in Immunology. She trained in internal medicine/rheumatology before completing her postdoctoral studies at the Mayo Clinic, Rochester, MN.

### **Non-employee directors**

*Shelley Chu, Ph.D.* has served on our board of directors since August 2021. Since November 2020, Dr. Chu has served as a partner of Lightspeed Venture Partners. Prior to Lightspeed, Dr. Chu served as Senior Director, R&D Strategy at Gilead from 2012 to 2015, where she led R&D strategy across all therapeutic areas and business development in immuno-oncology and HBV. She has served on the board of directors of several private companies, including Phathom Pharmaceuticals, Inc., Enlaza Therapeutics, Inc., Abata Therapeutics, Inc., 3T Biosciences, Inc., Medikine, Inc., Adanate, Inc., Scorpion Therapeutics, Inc., Tizona Therapeutics, Inc. (acquired by Gilead Sciences), Trishula Therapeutics, Inc. (partnered with AbbVie), SFJ Pharmaceuticals, Inc., IFM Therapeutics, Inc. (acquired by Bristol Myers Squibb), IFM Tre (acquired by Novartis), IFM Due (partnered with Novartis), IFM Quattro, Q32 Bio Inc., and Venatorx Pharmaceuticals, Inc. Dr. Chu holds an M.D. and a Ph.D. in Biochemistry and Biophysics from the University of California at San Francisco and a B.A. in Molecular Biology from Princeton University, where she serves as Co-Chair for Princeton ASC. She is also a member of the Scientific Advisory Board for BioCentury. Dr. Chu's investment experience in the biopharmaceutical industry as well as her experience on numerous public and private company boards of directors contributed to our board of directors' conclusion that she should serve as a director of our company.

*Julie Gerberding, M.D., M.P.H.* has served as a member of our board of directors since April 2021. Since December 2014, Dr. Gerberding has served as Executive Vice President and Chief Patient Officer at Merck & Co., Inc., where she is responsible for patient engagement, corporate social responsibility, ESG, and other functions. Formerly, Dr. Gerberding oversaw the communications and global public policy functions. She joined Merck in 2010 as president of vaccines and was instrumental in increasing access to the company's vaccines to people around the world. Previously, Dr. Gerberding was Director of the CDC, where she led the agency through SARS and over 40 emergency responses to public health crises. She serves on the boards of Cerner Corporation and MSD Wellcome Trust Hilleman Laboratories, a non-profit that develops new technologies for developing countries. She also co-chairs the CSIS Commission on Strengthening America's Health Security. Dr. Gerberding holds a B.A. in Chemistry/Biology and an M.D. from Case Western Reserve University and an M.P.H. from the University of California, Berkeley. She completed her internship and residency in Internal Medicine and fellowship in Clinical Pharmacology and Infectious Diseases at the University of California, San Francisco, where she is currently an Adjunct Associate Professor of Medicine. Dr. Gerberding's experience as an executive officer of a pharmaceutical company and experience on various boards of directors contributed to our board of directors' conclusion that she should serve as a director of our company.

*Patrick Heron* has served as a member of our board of directors since March 2020. Mr. Heron has served as Managing General Partner of Frazier Healthcare Partners since 1999. Prior to that, Mr. Heron helped develop McKinsey & Company's west coast biotechnology consulting practice. Mr. Heron has served on the boards of

## [Table of Contents](#)

directors of publicly-traded biopharmaceutical companies Arcutis Biotherapeutics, Inc. since April 2017, Mirum Pharmaceuticals, Inc. since November 2018, and Imago Biosciences, Inc. since October 2014 as well as several private companies. Mr. Heron holds a B.A. in Political Science from the University of North Carolina at Chapel Hill and an M.B.A. from Harvard Business School. Mr. Heron's investment experience in the biopharmaceutical industry as well as his experience on numerous public and private company boards of directors contributed to our board of directors' conclusion that he should serve as a director of our company.

*Jeryl Hilleman* has served as a member of our board of directors since April 2021. Ms. Hilleman brings extensive experience in life sciences and served as a public company CFO for close to 20 years. Most recently, From June 2014 to November 2019, Ms. Hilleman served as the Chief Financial Officer for Intersect ENT, Inc., a publicly-traded commercial drug delivery company focusing on patients with ear, nose and throat conditions. From September 2013 to May 2014, Ms. Hilleman served as Chief Financial Officer and Secretary of Ocera Therapeutics, Inc., a biopharmaceutical company, where she was responsible for managing Ocera's financial and accounting operations. From 2012 to 2013, Ms. Hilleman provided independent financial and strategic consulting for biotech and cleantech companies. From January 2008 to May 2012, she served as Chief Financial Officer of Amyris, Inc., a multinational, renewable products company based in California and Brazil, where she was responsible for managing Amyris' financial and accounting operations. Since December 2019, Ms. Hilleman has served as a member of the board of directors of SI-Bone, Inc. Since July 2018, Ms. Hilleman has served as a member of the board of directors of Minerva Neurosciences, Inc. and as a member of the board of directors of NovoCure Limited. From January 2005, Ms. Hilleman served as a member of the board of directors of Xenoport, Inc., a biopharmaceutical company, until it was acquired in July 2016. Ms. Hilleman received a B.A. in History from Brown University and an M.B.A. from the Wharton School at the University of Pennsylvania. Ms. Hilleman's financial experience, experience with biotechnology companies and her knowledge of our company contributed to our board of directors' conclusion that she should serve as a director of our company.

*Jaime Sepulveda, M.D., D.Sc., M.P.H.* has served as a member of our board of directors since February 2021. Since September 2011, Dr. Sepulveda, the Haile T. Debas Distinguished Professor of Global Health, has served as Executive Director of the UCSF Institute for Global Health Sciences. Prior to UCSF, he was a member of the Foundation Leadership Team at the Bill & Melinda Gates Foundation where he served as Director of Integrated Health Solutions, Director of Special Initiatives, and Senior Fellow in the Global Health Program from 2007 to 2011. During this time, Dr. Sepulveda also served as executive committee Chair and board Vice Chair of Gavi, the Vaccine Alliance. Previously, he served in the government of Mexico as Director General of the National Institute of Public Health, Dean of the National School of Public Health, Director of the National Institutes of Health, and Vice Minister of Health from 1985 to 2006. Dr. Sepulveda holds an M.S. in Public Health, a M.S. in Tropical Medicine and a Ph.D. from Harvard University. He received the Harvard Alumni Award of Merit and was elected to serve (2002-2008) at the Harvard Board of Overseers. He is also an elected member of the National Academy of Medicine and the American Academy of Arts and Sciences. Dr. Sepulveda's extensive experience as a professor in global health sciences and his understanding of our business contributed to our board of directors' conclusion that he should serve as a director of our company.

*Susan Silbermann* has served as a member of our board of directors since March 2021. From December 2018 to December 2020, Ms. Silbermann was the Global President for Emerging Markets at Pfizer and From June 2012 to December 2018, she was the Global President of Pfizer Vaccines. Throughout her 30-year career at Pfizer, Ms. Silbermann held numerous senior leadership positions in marketing, commercial and business development, and general management in the United States and multiple international markets. She has also served as a member of the board of Gavi, the Vaccine Alliance from August 2017 to August 2020, Vice Chair of the President's Advisory Council on Doing Business in Africa from June 2019 to March 2021, and an advisor to Catalyst Inc., a nonprofit organization that promotes inclusive workplaces for women around the world from January 2010 to January 2019. She is currently an advisor to the Malaria project at the TS Chan School of Public

## [Table of Contents](#)

Health at Harvard and a member of the board of Meet the Writers, a non-profit organization that brings inspiring and diverse authors and illustrators to New York City Public Schools. Ms. Silbermann holds a B.S. in Biology and B.A. in French from Tufts University and a joint M.B.A./M.A. degree in International Business and French Studies from the Stern Graduate School of Business and the Institute of French Studies at New York University. Ms. Silbermann's extensive vaccine experience and leadership roles at pharmaceutical companies contributed to our board of directors' conclusion that she should serve as a director of our company.

*Rajeev Venkayya, M.D.* has served on our board of directors since August 2021. Since September 2014, Dr. Venkayya has served as President of the Vaccine Business Unit at Takeda Pharmaceuticals. Prior to that, he served as Head of the Vaccine Business Unit since 2012. Prior to Takeda, from 2008 to 2011, Dr. Venkayya served as Director of Vaccine Delivery in the Global Health Program at the Bill & Melinda Gates Foundation, where he was responsible for the Foundation's efforts in polio eradication and new vaccine introduction. While at the foundation, he served on the board of the Global Alliance for Vaccines and Immunization. Dr. Venkayya was previously the Special Assistant to the President for Biodefense at the White House from 2005 to 2007. He also served as co-director of the Medical Intensive Care Unit and Director of the High-Risk Asthma Clinic at San Francisco General Hospital. He was Chief Medical Resident in internal medicine at the University of Michigan. Dr. Venkayya holds a B.S. and M.D. from the Northeast Ohio Universities College of Medicine, where he was inducted into the Alpha Omega Alpha honorary medical society. Dr. Venkayya's extensive experience as an officer of vaccine companies and his knowledge of our company contributed to our board of directors' conclusion that he should serve as a director of our company.

*Elise Wang* has served as a member of our board of directors since August 2021. Since January 2021, Ms. Wang has served as a Partner on the Public Structured Finance group at Deerfield Management Partners and joined Deerfield in 2010. Ms. Wang provides extensive research and analysis on individual companies operating in the healthcare industry in both the United States and Europe for Deerfield. Prior to joining Deerfield, from 2001 to 2007, Ms. Wang was a Senior Research Analyst and Managing Director in healthcare primarily covering the biotechnology industry at Citigroup. From 1996 to 2001, Ms. Wang was a Senior Research Analyst and Managing Director at PaineWebber Inc., where she covered biotechnology. Ms. Wang began her career in healthcare in 1987 as a venture capitalist and banker at PaineWebber Inc. and was an officer of PaineWebber Development Corporation, which managed entities invested in biotechnology and high technology companies. Ms. Wang currently serves on the board of directors of Jaguar Gene Therapy since July 2020, Axovia Therapeutics since February 2020 and Apertura Gene Therapy since May 2021. Ms. Wang holds an A.B. in Engineering Sciences with a specialty in Biomechanics from Harvard University and an M.B.A. from Harvard Business School. Ms. Wang's breadth of investment experience in the life sciences industry and her financial background contributed to our board of directors' conclusion that she should serve as a director of our company.

## **Board composition and election of directors**

### ***Director independence***

Our board of directors currently consists of nine members and, following the completion of this offering, will consist of seven members. Our board of directors has determined that all of our directors, other than Dr. Hershberg and \_\_\_\_\_, are independent directors in accordance with the listing requirements of the Nasdaq Global Market (Nasdaq). The Nasdaq independence definition includes a series of objective tests, including that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as required by Nasdaq rules, our board of directors has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our board of directors, would

## [Table of Contents](#)

interfere with the exercise of independent judgment in carrying out the responsibilities of the director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors or executive officers.

### **Classified board of directors**

In accordance with the terms of our amended and restated certificate of incorporation that will go into effect immediately prior to the closing of this offering, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the directors whose terms then expire will be eligible for reelection until the third annual meeting following reelection. Effective upon the closing of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_ and their terms will expire at our first annual meeting of stockholders following this offering;
- the Class II directors will be \_\_\_\_\_, \_\_\_\_\_ and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors will be \_\_\_\_\_, \_\_\_\_\_ and their terms will expire at our third annual meeting of stockholders following this offering.

Our amended and restated certificate of incorporation that will go into effect immediately prior to the closing of this offering will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our board of directors or a change in control of our company. Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of our outstanding voting stock then entitled to vote in an election of directors.

### **Board leadership structure**

Our board of directors is currently chaired by Dr. Hershberg, who also serves as our Chief Executive Officer. Our board of directors has determined that having an employee director serve as Chairman is in the best interest of our stockholders at this time because combining the roles allows one person to drive strategy and agenda-setting at the board level, as well as maintaining responsibility for executing on that strategy. Although we do not have a policy regarding the separation of the roles of Chief Executive Officer and Chairman of the board of directors, our board of directors believes that having the positions combined is the appropriate leadership structure for us at this time. We have a governance structure in place, including independent directors, designed to ensure the powers and duties of the dual role are handled responsibly. Our board of directors recognizes that, depending on the circumstances, other leadership models, such as separating the roles of Chief Executive Officer and Chairman, might be appropriate. Accordingly, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

### **Role of board in risk oversight process**

Our board of directors has responsibility for the oversight of our risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their

potential impact on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board of directors to understand our risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic and reputational risk.

The audit committee reviews information regarding liquidity and operations, and oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk assessment, risk management, loss prevention and regulatory compliance. Oversight by the audit committee includes direct communication with our external auditors, and discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor or control such exposures. The compensation committee is responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The nominating and corporate governance committee manages risks associated with the independence of the board of directors, corporate disclosure practices and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by our board of directors as a whole.

## **Board committees and independence**

Our board of directors has established three standing committees – audit, compensation and nominating and corporate governance – each of which operates under a charter that has been approved by our board of directors.

### ***Audit committee***

The audit committee's main function is to oversee our accounting and financial reporting processes and the audits of our financial statements. This committee's responsibilities include, among other things:

- appointing our independent registered public accounting firm;
- evaluating the qualifications, independence and performance of our independent registered public accounting firm;
- approving the audit and non-audit services to be performed by our independent registered public accounting firm;
- reviewing the design, implementation, adequacy and effectiveness of our internal accounting controls and our critical accounting policies;
- discussing with management and the independent registered public accounting firm the results of our annual audit and the review of our quarterly unaudited financial statements;
- reviewing, overseeing and monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters;
- reviewing on a periodic basis, or as appropriate, any investment policy and recommending to our board of directors any changes to such investment policy;
- reviewing with management and our auditors any earnings announcements and other public announcements regarding our results of operations;
- preparing the report that the SEC requires in our annual proxy statement;

## Table of Contents

- reviewing and approving any related party transactions and reviewing and monitoring compliance with our code of conduct and ethics; and
- reviewing and evaluating, at least annually, the performance of the audit committee and its members including compliance of the audit committee with its charter.

The members of our audit committee are \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_ serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. Our board of directors has determined that \_\_\_\_\_ is an “audit committee financial expert” as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq listing standards. Our board of directors has determined each of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_ is independent under the applicable rules of the SEC and Nasdaq. Upon the listing of our common stock on Nasdaq, the audit committee will operate under a written charter that satisfies the applicable standards of the SEC and Nasdaq.

### ***Compensation committee***

Our compensation committee approves policies relating to compensation and benefits of our officers and employees. The compensation committee approves corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other executive officers, evaluates the performance of these officers in light of those goals and objectives and approves the compensation of these officers based on such evaluations. The compensation committee also approves the issuance of stock options and other awards under our equity plans. The compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter.

The members of our compensation committee are \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_ serves as the chairperson of the committee. Our board of directors has determined that each of \_\_\_\_\_ and \_\_\_\_\_ is independent under the applicable Nasdaq listing standards and is a “non-employee director” as defined in Rule 16b-3 promulgated under the Exchange Act. Upon the listing of our common stock on Nasdaq, the compensation committee will operate under a written charter, which the compensation committee will review and evaluate at least annually.

### ***Nominating and corporate governance committee***

The nominating and corporate governance committee is responsible for assisting our board of directors in discharging the board of directors’ responsibilities regarding the identification of qualified candidates to become board members, the selection of nominees for election as directors at our annual meetings of stockholders (or special meetings of stockholders at which directors are to be elected), and the selection of candidates to fill any vacancies on our board of directors and any committees thereof. In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance policies, reporting and making recommendations to our board of directors concerning governance matters and oversight of the evaluation of our board of directors.

The members of our nominating and corporate governance committee are \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_ serves as the chairperson of the committee. Our board of directors has determined that each of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_ is independent under the applicable Nasdaq listing standards. Upon the listing of our common stock on Nasdaq, the nominating and corporate governance committee will operate under a written charter, which the nominating and corporate governance committee will review and evaluate at least annually.



## **Compensation committee interlocks and insider participation**

None of the members of our compensation committee has ever been one of our officers or employees. None of our executive officers currently serves, or has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

## **Board diversity**

Upon the closing of this offering, our nominating and corporate governance committee will be responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members) for election or appointment, the nominating and corporate governance committee and the board of directors will take into account many factors, including the following:

- personal and professional integrity, ethics and values;
- experience in corporate management, such as serving as an officer or former officer of a publicly-held company;
- experience as a board member or executive officer of another publicly-held company;
- strong finance experience;
- diversity of expertise and experience in substantive matters pertaining to our business relative to other board members;
- diversity of background and perspective, including, but not limited to, with respect to age, gender, race, place of residence and specialized experience;
- experience relevant to our business industry and with relevant social policy concerns; and
- relevant academic expertise or other proficiency in an area of our business operations.

Currently, our board of directors evaluates, and following the closing of this offering will evaluate, each individual in the context of the board of directors as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

## **Code of business conduct and ethics**

We plan to adopt a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, which will be effective upon the closing of this offering. Upon the closing of this offering, our code of business conduct and ethics will be available under the Corporate Governance section of our website at [www.hillevax.com](http://www.hillevax.com). In addition, we intend to post on our website all disclosures that are required by law or the listing standards of Nasdaq concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.



## Executive and director compensation

This section discusses the material components of the executive compensation program for our named executive officer who is named in the “Summary Compensation Table” below.

For 2020, our only “named executive officer” was Robert Hershberg, M.D., Ph.D, our Chairman, President and Chief Executive Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the closing of this offering may differ materially from the currently planned programs summarized in this discussion.

We are an “emerging growth company,” as that term is used in the JOBS Act, and have elected to comply with the reduced compensation disclosure requirements available to emerging growth companies under the JOBS Act.

### Summary compensation table

The following table presents summary information regarding the total compensation that was awarded to, earned by or paid to our named executive officer for services rendered during the year ended December 31, 2020.

Name and principal position	Year	Salary\$(1)	Bonus(\$)	Stock awards(\$)	All other compensation(\$)	Total(\$)
<i>Robert Hershberg, M.D., Ph.D. Chairman, President and Chief Executive Officer</i>	2020	388,258	—	—	—	388,258

(1) Dr. Hershberg served as an independent contractor and not an employee in fiscal year 2020. Amount reported as salary represents retainers paid to Dr. Hershberg for his consulting services during 2020.

### Narrative disclosure to summary compensation table

#### **Annual base salary**

The compensation of our executive officers is generally determined and approved at the time of their commencement of employment or service by our board of directors or the compensation committee.

During 2020 and through February 8, 2021, Dr. Hershberg was a consultant and received a monthly retainer of \$41,667.

Commencing with his commencement of employment on February 8, 2021, Dr. Hershberg’s annual base salary for his service as our Chief Executive Officer was \$500,000. His annual base salary was adjusted down to \$400,000 effective on September 1, 2021, subsequent to our entry into the Takeda License with Takeda and the closing of the August 2021 Note Financing, pursuant to his employment letter, as described below.

#### **Bonus compensation**

From time to time our board of directors or compensation committee may approve bonuses for our executive officers based on individual performance, company performance or as otherwise determined appropriate. No bonus plan was in effect during 2020.

Dr. Hershberg’s target annual bonus for 2021 is equal to 35% of his annual base salary, which annual bonus will be prorated to reflect the portion of the year following the closing of the August 2021 Note Financing.

### **Equity-based incentive awards**

Our equity-based incentive awards are designed to align our interests and the interests of our stockholders with those of our employees and consultants, including our named executive officer. We did not grant any equity awards during 2020.

Stock issuance to Dr. Hershberg and stock restriction agreement with Dr. Hershberg. On April 1, 2020, we issued and sold to Dr. Hershberg, 462,500 shares of our common stock for a per share purchase price of \$0.00105946, after giving effect to the 943.8776-for-1 forward stock split immediately prior to the Merger (these shares are referred to as the “Hershberg Founders’ Shares”).

On February 8, 2021, we entered into a stock restriction agreement with Dr. Hershberg whereby the Hershberg Founders’ Shares were subjected to new vesting conditions, such that 115,625 shares were deemed vested as of February 8, 2021 and the remaining 346,875 shares were converted into unvested shares of restricted stock that vest in equal monthly installments over the 48 months thereafter ending on February 8, 2025, subject, in each case, to continued employment or status as a service provider. Any unvested Hershberg Founders’ Shares held by Dr. Hershberg upon a termination of employment or service (after giving effect to any accelerated vesting provisions described further below), will be subject to repurchase by us at the original purchase price.

Under Dr. Hershberg’s stock restriction agreement, 100% of any unvested Hershberg Founders’ Shares will automatically accelerate and vest upon (1) a termination of his employment or service by us without cause or by him for good reason, (2) our failure to engage him as a consultant in connection with any mutually agreed upon termination of his employment or service as a member of our board of directors in a manner that ensures there is no break in his service to us for purposes of the stock restriction agreement, including any failure by us to execute the consulting agreement in the form attached to the stock restriction agreement prior to or concurrently with any such termination, and (3) his death or disability, in each case, subject to his continued employment or service through the date of such event.

For purposes of the stock restriction agreement with Dr. Hershberg:

- “cause” means: (1) his commission of an act of fraud, embezzlement or dishonesty, or the commission of some other illegal act, that has a demonstrable adverse impact on us or any successor or affiliate; (2) his conviction of, or plea of “guilty” or “no contest” to, a non-vehicular felony or any crime involving fraud, dishonesty or moral turpitude; (3) any intentional, unauthorized use or disclosure by him of our confidential information or trade secrets; (4) his gross negligence, insubordination or material violation of any duty of loyalty, or any other demonstrable material misconduct; (5) his ongoing and repeated failure or refusal to perform or neglect of duties as required by his employment or consulting agreement or comply with the reasonable and lawful instructions given by the board, which failure, refusal or neglect continues for 15 days of receiving written notice thereof (provided that it is understood that this clause (5) does not permit us to terminate Dr. Hershberg for cause solely because of his failure to meet specified performance objectives or achieve a specific result or outcome, or our dissatisfaction with the quality of services provided by him in the good faith performance of his duties to us); and (6) willful, material breach of any material company policy or any material provision of any employment or consulting agreement or any proprietary information and inventions assignment agreement; provided, that, in the case of clauses (4), (5) and (6), Dr. Hershberg shall receive written notice thereof and have an opportunity to remedy such breach.
- “disability” means the inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months.
- “good reason” means any of the following without his written consent: (1) a material diminution in his authority, duties or responsibilities, including, while Dr. Hershberg is an employee, a requirement that he

## [Table of Contents](#)

report to a corporate officer in lieu of the board; (2) a material diminution in his base compensation or consulting fees, unless such reduction is imposed across-the-board to senior management; (3) a material change in the geographic location at which he must perform his duties (and the parties acknowledge that a relocation of the geographic location at which he must perform his services to a location that increases his one-way commute from his residence by more than 50 miles from his principal place of employment prior to such relation will constitute a material change for purposes of this clause (3)); or (4) any other action or inaction that constitutes a material breach by us or any successor or affiliate of our obligations to him under the stock restriction agreement or any written employment or consulting agreement with the us or any successor or affiliate; provided, that, Dr. Hershberg's voluntary termination shall only constitute good reason if such termination occurs within six months following the initial existence of the act or failure to act constituting good reason.

*Stock issuance to David Socks and stock restriction agreement with Mr. Socks.* On June 27, 2019, North Bridge V issued and sold to a family trust of which David Socks, our Chief Financial Officer and Chief Business Officer, is a trustee (the "David Socks Trust"), 462,500 shares of North Bridge V common stock for a per share purchase price of \$0.00105946, after giving effect to the 943.8776-for-1 forward stock split immediately prior to Merger (the "Socks Founders' Shares").

On February 8, 2021, we entered into a stock restriction agreement with the David Socks Trust and Mr. Socks, whereby the Socks Founders' Shares were subjected to new vesting conditions, such that 115,625 shares were deemed vested as of February 8, 2021 and the remaining 346,875 shares were converted into unvested shares of restricted stock that vest in equal monthly installments over the 48 months thereafter ending on February 8, 2025, subject, in each case, to Mr. Socks' continued employment or status as a service provider. Any unvested Socks Founders' Shares held by the David Socks Trust upon a termination of Mr. Socks' employment or service (after giving effect to any accelerated vesting provisions described further below), will be subject to repurchase by us at the original purchase price. The terms of the stock restriction agreement with the David Socks Trust and Mr. Socks are substantially identical to the terms of the stock restriction agreement with Dr. Hershberg described above.

### **Employment letters with our executive officers**

Each of our executive officers' employment is "at will" and may be terminated at any time, subject to our contractual obligations to them as described below.

#### ***Employment letter with Dr. Hershberg***

We have entered into an employment letter with Dr. Hershberg, our President and Chief Executive Officer, setting forth the terms of his employment, effective February 8, 2021.

The employment letter for Dr. Hershberg provides for an annual base salary of \$500,000, which was adjusted down to \$400,000 effective September 1, 2021, subsequent to the closing of the August 2021 Note Financing, and an annual bonus with a target amount equal to 35% of Dr. Hershberg's annual base salary, which annual bonus will be prorated to reflect the portion of the year following the closing of the August 2021 Note Financing. Under the employment letter for Dr. Hershberg, he will devote at least 70% of his time to our company. Additionally, under the employment letter, Dr. Hershberg is eligible to participate in all employee benefit plans and programs generally available to similarly situated employees of our company and is entitled to vacation benefits in accordance with our policies.

Regardless of the manner in which Dr. Hershberg's employment terminates, he will be entitled to receive amounts previously earned during his term of employment, including unpaid salary and accrued but unused

## Table of Contents

vacation. In addition, Dr. Hershberg will be entitled to certain severance benefits under his employment letter, subject to his execution of a release of claims, return of all company property, compliance with post-termination obligations and resignation from positions with us.

Dr. Hershberg's employment letter provides for severance benefits for certain terminations that arise during and outside a change in control period (as defined below). Upon a termination without cause or resignation for good reason outside of a change in control period, Dr. Hershberg will be entitled to: (1) continuation of his base salary for 9 months (such applicable period, the "severance period"), (2) a lump sum equal to his target bonus for the year during which such termination occurs, prorated for the portion of the calendar year in which his termination occurs that has elapsed prior to such termination, plus any unpaid annual bonus for the calendar year prior to the year in which his termination occurs, to the extent he is entitled to such bonus and if such bonus has not already been paid, (3) payments of the COBRA premiums for his and his eligible dependents until the earliest of (a) the end of the severance period, (b) expiration of his eligibility for continuation coverage under COBRA, or (c) the date he becomes eligible for health insurance coverage in connection with his new employment, and (4) acceleration of the vesting of all outstanding equity awards that would have vested during the severance period (provided that Dr. Hershberg's Founders' Shares will be governed by his stock restriction agreement, as described above).

Upon a termination without cause or resignation for good reason that occurs within 24 months after a change in control (the "change in control period"), Dr. Hershberg will be entitled to all of the same severance benefits described above, except (1) the severance period is increased from 9 months to 12 months, (2) Dr. Hershberg will be entitled to a lump sum payment equal to his target bonus for the year during which such termination occurs, to the extent he is entitled to such bonus and if such bonus for the year during which such termination occurs, plus any unpaid annual bonus for the calendar year prior to the year in which his termination occurs, to the extent he is entitled to such bonus and if such bonus has not already been paid, and (3) all unvested and outstanding equity awards will become fully vested on the effective date of his release (provided that Dr. Hershberg's Founders' Shares will be governed by his stock restriction agreement, as described above).

For purposes of Dr. Hershberg's employment letter:

- "cause" means (1) his commission of an act of fraud, embezzlement or dishonesty, or the commission of some other illegal act, that has a demonstrable adverse impact on us or any successor or affiliate; (2) his conviction of, or plea of "guilty" or "no contest" to, a non-vehicular felony or any crime involving fraud, dishonesty or moral turpitude; (3) any intentional, unauthorized use or disclosure by him of our confidential information or trade secrets; (4) his gross negligence, insubordination or material violation of any duty of loyalty to us or any successor or affiliate thereof, or any other demonstrable material misconduct on his part; (5) his ongoing and repeated failure or refusal to perform or neglect of his duties as required by the employment letter or comply with the reasonable and lawful instructions given by the board, which failure, refusal or neglect continues for 15 days following his receipt of written notice from the board of directors stating with specificity the nature of such failure, refusal or neglect (provided that it is understood that this clause (5) does not permit us to terminate Dr. Hershberg for cause solely because of his failure to meet specified performance objectives or achieve a specific result or outcome, or our dissatisfaction with the quality of services provided by him in the good faith performance of his duties to us); or (6) his willful, material breach of any material company policy or any material provision of the employment letter or his proprietary information and inventions assignment agreement; provided, that, in the case of clauses (4), (5) and (6), Dr. Hershberg shall receive written notice thereof and have an opportunity to remedy such breach.
- "change in control" has the same meaning given to such term in our 2021 Equity Incentive Plan (the 2021 Plan); and

## Table of Contents

- “good reason” means any of the following without his written consent: (1) a material diminution in his authority, duties or responsibilities, including a requirement that he report to a corporate officer in lieu of the board; (2) a material diminution in his base compensation (and any diminution of 10% or more shall be considered material for this purpose, regardless of whether such diminution occurs due to a single reduction or a series of reductions in his base compensation), unless such a reduction is imposed across-the-board to senior management; (3) a material change in the geographic location at which he must perform his duties (and the parties acknowledge that a relocation of the geographic location at which he must perform his services to a location that increases his one-way commute from his residence by more than 50 miles from his principal place of employment prior to such relation will constitute a material change for purposes of this clause (3)); or (4) any other action or inaction that constitutes a material breach by us or any successor or affiliate of its obligations to him under the employment letter or his stock restriction agreement. Dr. Hershberg must provide written notice to us of the occurrence of any of the foregoing events or conditions without his written consent within 6 months of the occurrence of such event, and we will have 30 days to cure such event or condition after receipt of written notice from Dr. Hershberg. Dr. Hershberg’s resignation for good reason must occur within 30 days following the expiration of the 30-day cure period.

### **Employment letters with other executives**

#### *Employment letters with Dr. Kohli and Mr. Socks*

We entered into employment letters with each of Dr. Kohli and Mr. Socks setting forth the terms of their employment as our Chief Operating Officer and Chief Financial Officer, Chief Business Officer and Treasurer, respectively.

The employment letter for Dr. Kohli provides for an annual base salary of \$200,000, which adjusted up to \$400,000 on March 1, 2021, and an annual bonus with a target amount equal to 35% of Dr. Kohli’s annual base salary. Under the employment letter for Dr. Kohli, he will devote at least 70% of his time to our company. Additionally, under the employment letter, Dr. Kohli is eligible to participate in all employee benefit plans and programs generally available to similarly situated employees of our company and is entitled to vacation benefits in accordance with our policies.

The employment letter for Mr. Socks provides for an annual base salary of \$200,000, which was increased to \$400,000 on March 1, 2021, and an annual bonus with a target amount equal to 35% of Mr. Socks’ annual base salary. Under the employment letter for Mr. Socks, he will devote at least 70% of his time to our company. Additionally, under the employment letter, Mr. Socks is eligible to participate in all employee benefit plans and programs generally available to similarly situated employees of our company and is entitled to vacation benefits in accordance with our policies.

Regardless of the manner in which each executive’s employment terminates, he will be entitled to receive amounts previously earned during his term of employment, including unpaid salary and accrued but unused vacation. In addition, each executive will be entitled to certain severance benefits under his employment letter, subject to execution of a release of claims, return of all company property, compliance with post-termination obligations and resignation from positions with us.

The executive employment letters provide for severance benefits for certain terminations that arise during and outside a change in control period (as defined below). Upon a termination without cause or resignation for good reason outside of a change in control period, an executive will be entitled to: (1) continuation of his base salary for 9 months (such applicable period, the “severance period”), (2) a lump sum equal to his target bonus for the year during which such termination occurs, plus any unpaid annual bonus for the calendar year prior to the year in which his termination occurs, to the extent he is entitled to such bonus and if such bonus has not already been paid, (3) payments of the COBRA premiums for his and his eligible dependents until the earliest of

## [Table of Contents](#)

(a) the end of the severance period, (b) expiration of his eligibility for continuation coverage under COBRA, or (c) the date he becomes eligible for health insurance coverage in connection with his new employment, and (4) acceleration of the vesting of all outstanding equity awards that would have vested during the severance period (provided that, with respect to Mr. Socks, the Socks Founders' Shares will be governed by his stock restriction agreement, as described above).

Upon a termination without cause or resignation for good reason that occurs 24 months after a change in control (the "change in control period"), an executive will be entitled to all of the same severance benefits described above, except (1) the severance period is increased from 9 months to 12 months, (2) the executive will be entitled to a lump sum payment equal to his target bonus for the year during which such termination occurs, to the extent he is entitled to such bonus and if such bonus for the year during which such termination occurs, plus any unpaid annual bonus for the calendar year prior to the year in which his termination occurs, to the extent he is entitled to such bonus and if such bonus has not already been paid, and (3) all unvested and outstanding equity awards will become fully vested on the effective date of his release (provided that, with respect to Mr. Socks, the Socks Founders' Shares will be governed by his stock restriction agreement, as described above).

For purposes of the executive employment letters, the terms "cause," "change in control" and "good reason" generally have the same meanings as those described above for Dr. Hershberg's employment letter.

### ***Employment agreement with Dr. Borkowski***

We entered into an employment agreement with Dr. Borkowski setting forth the terms of her employment, effective May 1, 2021.

The employment agreement with Dr. Borkowski provides for an annual base salary of CHF 355,000, and an annual bonus with a target amount equal to 30% of Dr. Borkowski's annual base salary. Under the employment agreement for Dr. Borkowski, her employment is on a full-time basis, with her principal place of work being Zurich, Switzerland, with the agreement that she will work approximately two weeks out of every month in the Greater Boston area. Additionally, under the employment agreement, Dr. Borkowski is generally eligible to participate in employee benefit plans and programs available to similarly situated employees at our company and is entitled to four weeks of paid vacation per year.

The employment agreement also provides for an indefinite term of employment, which may be terminated by either party upon nine months' notice. Upon the termination of her employment, Dr. Borkowski is subject to a one year non-competition period covering the territories of Switzerland and Germany, during which the company will pay Dr. Borkowski monthly compensation equal to 100% of her monthly gross salary. A violation of this non-competition period will result in Dr. Borkowski owing liquidated damages to the company in the amount of 50% of the annual base salary for each instance of violation. The company also reserves the right to request, by way of specific performance, that Dr. Borkowski cease and desist any activity which violates the non-competition provision. Dr. Borkowski is also subject to a one year non-solicitation provision following her termination.

### **Outstanding equity awards at fiscal year-end**

Our named executive officer did not hold any equity awards as of December 31, 2020.

### **Other elements of compensation**

#### ***Perquisites, health, welfare and retirement benefits***

Our executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life, disability and accidental death and dismemberment insurance plans, in each case on the

## [Table of Contents](#)

generally on same basis as all of our other employees. We generally do not provide perquisites or personal benefits to our named executive officer, except in limited circumstances. Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

### ***Nonqualified deferred compensation***

We do not maintain nonqualified defined contribution plans or other nonqualified deferred compensation plans. Our board of directors may elect to provide our officers and other employees with non-qualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

### ***Severance and change in control benefits***

Our executive officers may become entitled to certain benefits or enhanced benefits upon a qualifying termination of employment, including in connection with a change in control, pursuant to their employment letters. In addition, the stock restriction agreements with Dr. Hershberg and the David Socks Trust provide for accelerated vesting of all outstanding Hershberg Founders' Shares and Socks Founders' Shares, respectively, upon a qualifying termination. For additional discussion, please see "—Equity-Based Incentive Awards" and "—Employment Letters with our Executive Officers" above.

## **Incentive award plans**

### ***2022 incentive award plan***

Effective the day prior to the first public trading date of our common stock, we intend to adopt and ask our stockholders to approve the 2022 Plan under which we may grant cash and equity based incentive awards to eligible service providers in order to attract, retain and motivate the persons who make important contributions to the company. The material terms of the 2022 Plan, as it is currently contemplated, are summarized below. Our board of directors is still in the process of developing, approving and implementing the 2022 Plan and, accordingly, this summary is subject to change.

***Shares available.*** The number of shares initially available for issuance under awards granted pursuant to the 2022 Plan will be the sum of (1) \_\_\_\_\_ shares of our common stock, plus (2) 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 beginning in 2022 and ending in and including 2031, equal to the lesser of (1) \_\_\_\_\_ % 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 our board of directors. No more than \_\_\_\_\_ shares of common stock may be issued upon the exercise of incentive stock options under the 2022 Plan. Shares available under the 2022 Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares.

If an award under the 2022 Plan expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, or canceled without having been fully exercised or forfeited, any unused shares subject to the award will, as applicable, become or again be available for new grants under the 2022 Plan. Awards granted under the 2022 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which we enter into a merger or similar corporate transaction will not reduce the shares available for grant under the 2022 Plan.

***Eligibility and administration.*** Our employees, consultants and directors, and employees and consultants of our subsidiaries will be eligible to receive awards under the 2022 Plan. The 2022 Plan will be administered by



## [Table of Contents](#)

our board of directors with respect to awards to non-employee directors and by our compensation committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to the limitations that may be imposed under the 2022 Plan, Section 16 of the Exchange Act, stock exchange rules and other applicable laws. The plan administrator will have the authority to take all actions and make all determinations under the 2022 Plan, to interpret the 2022 Plan and award agreements and to adopt, amend and repeal rules for the administration of the 2022 Plan as it deems advisable. The plan administrator will also have the authority to determine which eligible service providers receive awards, grant awards and set the terms and conditions of all awards under the 2022 Plan, including any vesting and vesting acceleration provisions, subject to the conditions and limitations in the 2022 Plan.

**Awards.** The 2022 Plan provides for the grant of stock options, including incentive stock options (ISOs), and nonqualified stock options (NSOs), restricted stock, dividend equivalents, restricted stock units (RSUs), stock appreciation rights (SARs), and other stock or cash-based awards. Certain awards under the 2022 Plan may constitute or provide for payment of “nonqualified deferred compensation” under Section 409A of the Code. All awards under the 2022 Plan will be set forth in award agreements, which will detail the terms and conditions of awards, including any applicable vesting and payment terms and post-termination exercise limitations. A brief description of each award type follows.

- **Stock options and SARs.** Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. The exercise price of a stock option will not be less than 100% of the fair market value of the underlying share on the date of grant (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders). Vesting conditions determined by the plan administrator may apply to stock options and may include continued service, performance and/or other conditions. ISOs generally may be granted only to our employees and employees of our parent or subsidiary corporations, if any. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a SAR will not be less than 100% of the fair market value of the underlying share on the date of grant (except with respect to certain substitute SARs granted in connection with a corporate transaction), and the term of a SAR may not be longer than ten years. Vesting conditions determined by the plan administrator may apply to SARs and may include continued service, performance and/or other conditions.
- **Restricted stock and RSUs.** Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met, and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on shares of our common stock prior to the delivery of the underlying shares. The plan administrator may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to restricted stock and RSUs will be determined by the plan administrator, subject to the conditions and limitations contained in the 2022 Plan.
- **Other stock or cash based awards.** Other stock or cash-based awards are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock or other property. Other stock or cash-based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone

payments and as payment in lieu of compensation to which a participant is otherwise entitled. The plan administrator will determine the terms and conditions of other stock or cash based awards, which may include any purchase price, performance goal, transfer restrictions and vesting conditions.

*Performance criteria.* The plan administrator may select performance criteria for an award to establish performance goals for a performance period. Performance criteria under the 2022 Plan may include, but are not limited to, the following: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including but not limited to gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on stockholders' equity; total stockholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals also may be based solely by reference to the company's performance or the performance of a subsidiary, division, business segment or business unit of the company or a subsidiary, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies. When determining performance goals, the plan administrator may provide for exclusion of the impact of an event or occurrence which the plan administrator determines should appropriately be excluded, including, without limitation, non-recurring charges or events, acquisitions or divestitures, changes in the corporate or capital structure, events unrelated to the business or outside of the control of management, foreign exchange considerations, and legal, regulatory, tax or accounting changes.

*Certain transactions.* In connection with certain corporate transactions and events affecting our common stock, including a change in control, or change in any applicable laws or accounting principles, the plan administrator has broad discretion to take action under the 2022 Plan to prevent the dilution or enlargement of intended benefits, facilitate the transaction or event or give effect to the change in applicable laws or accounting principles. This includes canceling awards for cash or property, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares subject to outstanding awards and/or with respect to which awards may be granted under the 2022 Plan and replacing or terminating awards under the 2022 Plan. In addition, in the event of certain non-reciprocal transactions with our stockholders, the plan administrator will make equitable adjustments to the 2022 Plan and outstanding awards as it deems appropriate to reflect the transaction. In the event of a change in control of the company (as defined in the 2022 Plan), to the extent that the surviving entity declines to continue, convert, assume or replace outstanding awards, then all such awards may become fully vested and exercisable in connection with the transaction. Individual award agreements may provide for additional accelerated vesting and payment provisions.

*Provisions of the 2022 plan relating to director compensation.* The 2022 Plan provides that the plan administrator may establish compensation for non-employee directors from time to time subject to the 2022 Plan's limitations. Prior to commencing this offering, we intend to approve and implement a compensation program for our non-employee directors. Our board of directors or its authorized committee may modify the non-employee director compensation program from time to time in the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, provided that the sum of any cash compensation or other compensation and the grant date fair value of any equity awards granted under the 2022 Plan as compensation for services as a non-employee director during any fiscal year may not exceed \$ (increased to \$ in the calendar year of a non-employee director's initial service as a non-employee director or any calendar year in which a non-employee director serves as chairman of the board or lead independent director for any portion of such year), which limits shall not apply to the compensation for any non-employee director who serves in any capacity in addition to that of a non-employee director for which he or she receives additional compensation or any compensation paid to any non-employee director prior to the first calendar year following the completion of this offering. The plan administrator may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the plan administrator may determine in its discretion, subject to the limitations in the 2022 Plan.

*Foreign participants, clawback provisions, transferability and participant payments.* The plan administrator may modify awards granted to participants who are foreign nationals or employed outside the United States or establish subplans or procedures to address differences in laws, rules, regulations or customs of such foreign jurisdictions. All awards will be subject to any company claw back policy as set forth in such claw back policy or the applicable award agreement. Except as the plan administrator may determine or provide in an award agreement, awards under the 2022 Plan are generally non transferrable, except by will or the laws of descent and distribution, or, subject to the plan administrator's consent, pursuant to a domestic relations order and are generally exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2022 Plan and exercise price obligations arising in connection with the exercise of stock options under the 2022 Plan, the plan administrator may, in its discretion, accept cash, wire transfer or check, shares of our common stock that meet specified conditions, a promissory note, a "market sell order," such other consideration as the plan administrator deems suitable or any combination of the foregoing.

*Plan amendment and termination.* Our board of directors may amend or terminate the 2022 Plan at any time; however, no amendment, other than an amendment that increases the number of shares available under the 2022 Plan, may materially and adversely affect an award outstanding under the 2022 Plan without the consent of the affected participant and stockholder approval will be obtained for any amendment to the extent necessary to comply with applicable laws. Further, the plan administrator may, without the approval of our stockholders, amend any outstanding stock option or SAR to reduce its price per share, other than in the context of corporate transactions or equity restructurings, as described above. The 2022 Plan will remain in effect until the tenth anniversary of its effective date, unless earlier terminated by our board of directors. No awards may be granted under the 2022 Plan after its termination.

#### **2021 equity incentive plan**

On February 8, 2021, our board of directors and our stockholders approved the adoption of the 2021 Plan.

A total of 1,766,500 shares of our common stock are reserved for issuance under the 2021 Plan. As of September 30, 2021, 929,500 shares of our common stock were subject to outstanding restricted stock awards under the 2021 Plan, no options to purchase shares of our common stock have been granted under the 2021 Plan, and 837,000 shares of our common stock remained available for future issuance under the 2021 Plan.

## [Table of Contents](#)

After the effective date of the 2022 Plan, no additional awards will be granted under the 2021 Plan. However, the 2021 Plan will continue to govern the terms and conditions of the outstanding awards granted under it. Shares of our common stock subject to awards granted under the 2021 Plan that expire, lapse or are terminated, exchanged for cash, surrendered, repurchased or forfeited following the effective date of the 2021 Plan will be available for issuance under the 2022 Plan in accordance with its terms.

*Administration.* Our board of directors administers the 2021 Plan, unless it delegates authority for administration of the plan. Subject to the terms and conditions of the 2021 Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the type or types of awards to be granted to each person, determine the number of awards to grant, determine the number of shares to be subject to such awards, and the terms and conditions of such awards, and make all other determinations and decisions and to take all other actions necessary or advisable for the administration of the 2021 Plan. The plan administrator is also authorized to establish, adopt, amend or revise rules relating to administration of the 2021 Plan, subject to certain restrictions.

*Eligibility.* Awards under the 2021 Plan may be granted to individuals who are then our employees, consultants and members of our board of directors and our subsidiaries. Only employees may be granted ISOs.

*Awards.* The 2021 Plan provides that our administrator may grant or issue stock options (including NSOs and ISOs), restricted stock, RSUs, other stock-based awards, or any combination thereof. The administrator considers each award grant subjectively, considering factors such as the individual performance of the recipient and the anticipated contribution of the recipient to the attainment of our long-term goals. Each award is set forth in a separate agreement with the person receiving the award and indicates the type, terms and conditions of the award.

*Certain transactions.* The plan administrator has broad discretion to equitably adjust the provisions of the 2021 Plan and the terms and conditions of existing and future awards, including with respect to aggregate number and type of shares subject to the 2021 Plan and awards granted pursuant to the 2021 Plan, to prevent the dilution or enlargement of intended benefits and/or facilitate necessary or desirable changes in the event of certain transactions and events affecting our common stock, such as stock dividends, stock splits, mergers, acquisitions, consolidations and other corporate transactions. The plan administrator may also provide for the acceleration, cash-out, termination, assumption, substitution or conversion of awards in the event of a change in control or certain other unusual or nonrecurring events or transactions. In addition, in the event of certain non-reciprocal transactions with our stockholders, or an "equity restructuring," the plan administrator will make equitable adjustments to the 2021 Plan and outstanding awards as it deems appropriate to reflect the equity restructuring.

In the event of a change of control where the acquirer does not assume awards granted under the 2021 Plan, awards issued under the 2021 Plan held by persons who have not experienced a termination of service will be subject to accelerated vesting such that 100% of the awards will become vested and exercisable or payable, as applicable, immediately prior to the change in control. Under the 2021 Plan, a change of control is generally defined as: (1) a merger or consolidation of our company with or into any other corporation or other entity or person; (2) a sale, lease, exchange or other transfer in one transaction or a series of related transactions of all or substantially all of our company's assets; or (3) any other transaction, including the sale by us of new shares of our capital stock or a transfer of existing shares of our capital stock, the result of which is that a third party that is not an affiliate of us or our stockholders (or a group of third parties not affiliated with us or our stockholders) immediately prior to such transaction acquires or holds capital stock representing a majority of our outstanding voting power immediately following such transaction; provided that the following events shall not constitute a "change in control" under the 2021 Plan: (a) a transaction (other than a sale of all or substantially all of our assets) in which the holders of our voting securities immediately prior to the merger or

consolidation hold, directly or indirectly, at least a majority of the voting securities in the successor corporation or its parent immediately after the merger or consolidation; (b) a sale, lease, exchange or other transaction in one transaction or a series of related transactions of all or substantially all of our assets to an affiliate of ours; (c) an initial public offering of any of our securities or any other transaction principally for bona fide equity financing purposes; (d) a reincorporation solely to change our jurisdiction; or (e) a transaction undertaken for the primary purpose of creating a holding company that will be owned in substantially the same proportion by the persons who held our securities immediately before such transaction.

*Plan amendment and termination.* Our board of directors may terminate, amend or modify the 2021 Plan. However, stockholder approval of any amendment to the 2021 Plan must be obtained to the extent necessary and desirable to comply with any applicable law, regulation or stock exchange rule, or for any amendment to the 2021 Plan that increases the number of shares available under the 2021 Plan.

### **2022 employee stock purchase plan**

Effective the day prior to the first public trading date of our common stock, we intend to adopt and ask our stockholders to approve the 2022 Employee Stock Purchase Plan, or the 2022 ESPP. The material terms of the 2022 ESPP, as it is currently contemplated, are summarized below. Our board of directors is still in the process of developing, approving and implementing the 2022 ESPP and, accordingly, this summary is subject to change.

The 2022 ESPP is comprised of two distinct components in order to provide increased flexibility to grant options to purchase shares under the 2022 ESPP to U.S. and to non-U.S. employees. Specifically, the 2022 ESPP authorizes (1) the grant of options to U.S. employees that are intended to qualify for favorable U.S. federal tax treatment under Section 423 of the Code, (the "Section 423 Component"), and (2) the grant of options that are not intended to be tax-qualified under Section 423 of the Code to facilitate participation for employees located outside of the U.S. who do not benefit from favorable U.S. federal tax treatment and to provide flexibility to comply with non-U.S. law and other considerations (the "Non-Section 423 Component"). Where permitted under local law and custom, we expect that the Non-Section 423 Component will generally be operated and administered on terms and conditions similar to the Section 423 Component.

*Shares available; administration.* A total of \_\_\_\_\_ shares of our common stock will initially be 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 beginning in 2022 and ending in and including 2031, by an amount equal to the lesser of (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 our board of directors, provided that no more than \_\_\_\_\_ shares of our common stock may be issued under the 2022 ESPP. Our board of directors or a committee of our board of directors will administer and will have authority to interpret the terms of the 2022 ESPP and determine eligibility of participants. We expect that the compensation committee will be the initial administrator of the 2022 ESPP.

*Eligibility.* We expect that all of our employees will be eligible to participate in the 2022 ESPP. However, an employee may not be granted rights to purchase stock under our 2022 ESPP if the employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our stock.

*Grant of rights.* Stock will be offered under the 2022 ESPP during offering periods. The length of the offering periods under the 2022 ESPP will be determined by the plan administrator and may be up to 27 months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The purchase dates for each offering period will be the final trading day in the offering period. Offering periods under the 2022 ESPP will commence when determined by the plan administrator. The plan administrator may,

## [Table of Contents](#)

in its discretion, modify the terms of future offering periods. In non-U.S. jurisdictions where participation in the 2022 ESPP through payroll deductions is prohibited, the plan administrator may provide that an eligible employee may elect to participate through contributions to the participant's account under the 2022 ESPP in a form acceptable to the 2022 ESPP administrator in lieu of or in addition to payroll deductions.

The 2022 ESPP permits participants to purchase common stock through payroll deductions of up to a specified percentage of their eligible compensation. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period. In addition, no employee will be permitted to accrue the right to purchase stock under the Section 423 Component at a rate in excess of \$25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant will automatically be granted an option to purchase shares of our common stock. The option will expire at the end of the applicable offering period, and will be exercised at that time to the extent of the payroll deductions accumulated during the offering period. The purchase price of the shares, in the absence of a contrary designation, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the purchase date. Participants may voluntarily end their participation in the 2022 ESPP at any time during a specified period prior to the end of the applicable offering period, and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon a participant's termination of employment.

A participant may not transfer rights granted under the 2022 ESPP other than by will or the laws of descent and distribution, and are generally exercisable only by the participant.

*Certain transactions.* In the event of certain non-reciprocal transactions or events affecting our common stock, the plan administrator will make equitable adjustments to the 2022 ESPP and outstanding rights. In the event of certain unusual or non-recurring events or transactions, including a change in control, the plan administrator may provide for (1) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (2) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (3) the adjustment in the number and type of shares of stock subject to outstanding rights, (4) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods or (5) the termination of all outstanding rights.

*Plan amendment and termination.* The plan administrator may amend, suspend or terminate the 2022 ESPP at any time. However, stockholder approval will be obtained for any amendment that increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the 2022 ESPP or changes the corporations or classes of corporations whose employees are eligible to participate in the 2022 ESPP.

## **Director compensation**

Historically, we have not paid cash or stock-based compensation to directors for their service on our board of directors.

On April 10, 2019, YamadaCo III, Inc. issued and sold to Dr. Yamada, 462,500 shares of common stock of YamadaCo III, Inc. for a per share purchase price of \$0.00105946, after giving effect to the Merger.

On February 8, 2021, we entered into a stock restriction agreement with Dr. Yamada whereby Dr. Yamada's previously-acquired 462,500 shares of our common stock were subjected to new vesting conditions, such that 115,625 shares were deemed vested as of February 8, 2021 and the remaining 346,875 shares were converted into unvested shares of restricted stock that were scheduled to vest in equal monthly installments over the



## [Table of Contents](#)

48 months thereafter ending on February 8, 2025, subject, in each case, to continued employment or status as a service provider. Any unvested shares held by Dr. Yamada upon a termination of employment or service (after giving effect to any accelerated vesting provisions described further below), were subject to repurchase by us at the original purchase price.

Under Dr. Yamada's stock restriction agreement, 100% of any unvested shares automatically accelerated and vested upon his death. In connection with Dr. Yamada's passing on August 4, 2021, all unvested shares of restricted stock held by Dr. Yamada as of such date were accelerated in full.

### ***Post-initial public offering director compensation program***

In connection with this offering, we intend to adopt and ask our stockholders to approve the initial terms of our non-employee director compensation program. The material terms of the non-employee director compensation program, as it is currently contemplated, are summarized below.

The non-employee director compensation program will provide for annual retainer fees and/or long-term equity awards for our non-employee directors. We expect each non-employee director will receive an annual retainer of \$ . Non-employee directors serving as the chairs of the audit, compensation and nominating and corporate governance committees will receive additional annual retainers of \$ , \$ and \$ , respectively. Non-employee directors serving as members of the audit, compensation and nominating and corporate governance committees will receive additional annual retainers of \$ , \$ and \$ , respectively. The non-employee directors will also receive initial grants of options to purchase shares of our common stock upon election to the board of directors, which will vest in equal monthly installments over the three years following the date of grant, and thereafter annual grants of options to purchase shares of our common stock, vesting in equal monthly installments over the 12 months following the date of grant (or, if earlier, on the next occurring annual meeting of our stockholders), in each case, subject to the non-employee director continuing in service on our board of directors through such vesting dates.

Compensation under our non-employee director compensation program will be subject to the annual limits on non-employee director compensation set forth in the 2022 Plan, as described above. Our board of directors or its authorized committee may modify the non-employee director compensation program from time to time in the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, subject to the annual limit on non-employee director compensation set forth in the 2022 Plan. As provided in the 2022 Plan, our board of directors or its authorized committee may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the board of directors or its authorized committee may determine in its discretion, provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation or in other compensation decisions involving non-employee directors.

### **Limitations of liability and indemnification matters**

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law, which prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.



## [Table of Contents](#)

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that if Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that we shall have the power to indemnify our employees and agents to the fullest extent permitted by law. Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our amended and restated bylaws would permit indemnification. We have obtained directors' and officers' liability insurance.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. These agreements, among other things, provide for indemnification of our directors and executive officers for expenses, judgments, fines and settlement amounts incurred by this person in any action or proceeding arising out of this person's services as a director or executive officer or at our request. We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers.

The above description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is not complete and is qualified in its entirety by reference to these documents, each of which is filed as an exhibit to the registration statement of which this prospectus is a part.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

## Certain relationships and related person transactions

The following includes a summary of transactions since our inception to which we have been a party in which the amount involved exceeded or will exceed the lesser of \$120,000 and one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders. The transactions below also include transactions of North Bridge V, Inc. and YamadaCo III, Inc. prior to the Merger. We also describe below certain other transactions with our directors, executive officers and stockholders.

### Convertible promissory note financings

#### *Prior convertible promissory note financings with Frazier Life Sciences IX, L.P. and Frazier Life Sciences X, L.P.*

In April 2019, YamadaCo III, Inc. entered into a convertible promissory note purchase agreement with Frazier Life Sciences IX, L.P. (FLS IX), as amended in October 2020, pursuant to which from April 2019 through September 2019 YamadaCo III issued and sold to FLS IX two convertible promissory notes and from March 2020 through October 2020, YamadaCo III issued and sold to Frazier Life Sciences X, L.P. (FLS X) two convertible promissory notes (collectively, the YamadaCo Notes), in the aggregate principal amount of approximately \$1.3 million. On March 31, 2020, YamadaCo III, FLS IX and FLS X entered into a Securities Transfer Agreement (the YamadaCo Securities Transfer Agreement), pursuant to which the convertible promissory notes issued to FLS IX in 2019 were transferred to FLS X and FLS IX assigned all of its rights, remedies, obligations or liabilities under the convertible note purchase agreement to FLS X. The YamadaCo Notes accrued interest at the issuance date applicable federal rate (2.52%, 1.85%, 1.50% and 0.14%, respectively) per annum, and were due and payable upon demand by FLS X 12 months from the date of transfer for the convertible promissory notes issued in 2019, and 12 months from the date of issuance for the convertible promissory notes issued in 2020, subject to earlier conversion or repayment in the event YamadaCo III completed an equity financing or a change of control.

In May 2019, North Bridge V, Inc. entered into a convertible note purchase agreement FLS IX, pursuant to which in May 2019 North Bridge V issued and sold to FLS IX a convertible promissory note and from March 2020 through August 2020, North Bridge V issued and sold to FLS X two convertible promissory notes (collectively, the North Bridge Notes), in the aggregate principal amount of approximately \$0.4 million. On March 31, 2020, North Bridge V, FLS IX and FLS X entered into a Securities Transfer Agreement (the North Bridge Securities Transfer Agreement), pursuant to which the convertible promissory notes issued to FLS IX in 2019 were transferred to FLS X and FLS IX assigned all of its rights, remedies, obligations or liabilities under the convertible note purchase agreement to FLS X. The North Bridge Notes accrued interest at the issuance date applicable federal rate (2.39%, 1.50% and 0.17%, respectively) per annum, and were due and payable upon demand by FLS X 12 months from the date of transfer for the convertible promissory note issued in 2019, and 12 months from the date of issuance for the convertible promissory notes issued in 2020, subject to earlier conversion or repayment in the event North Bridge completed an equity financing or a change of control.

In March 2020, we entered into a convertible note purchase agreement with FLS X, pursuant to which in March 2020 we issued and sold to FLS X a convertible promissory note (the March 2020 HilleVax Note), in the principal amount of \$0.5 million. The March 2020 HilleVax Note accrued interest at the issuance date applicable federal rate (1.50%) per annum, and was due and payable upon demand by FLS X 18 months from the date of issuance, subject to earlier conversion or repayment in the event we completed an equity financing or a change of control.

## Table of Contents

In April 2021, we entered into a convertible note purchase agreement with FLS X, as amended in June 2021 and July 2021, pursuant to which from April 2021 through June 2021 we issued and sold to FLS X three convertible promissory notes (the April 2021 HilleVax Notes), in the principal amount of \$1.75 million. Each of the April 2021 HilleVax Notes accrued interest at the issuance date applicable federal rate (0.12%) per annum, and were due and payable upon demand by FLS X 18 months from the date of issuance, subject to earlier conversion or repayment in the event we completed an equity financing or a change of control.

In July 2021, we entered into a convertible note purchase agreement with FLS X, pursuant to which in July 2021 we issued and sold to FLS X a convertible promissory note (the July 2021 HilleVax Note), in the principal amount of \$4.5 million. The July 2021 HilleVax Note accrued interest at the issuance date applicable federal rate (0.12%) per annum, and was due and payable upon demand by FLS X 18 months from the date of issuance, subject to earlier conversion or repayment in the event we completed an equity financing or a change of control.

The YamadaCo Notes, the North Bridge Notes, the March 2020 HilleVax Note, the April 2021 HilleVax Notes and the July 2021 HilleVax Note, in the aggregate amount of approximately \$8.5 million, including accrued interest thereon, were cancelled and exchanged for August 2021 Notes issued in the August 2021 convertible note financing described below.

The general partner of FLS X is FHMLS X, L.P., and the general partner of FHMLS X, L.P. is FHMLS X, L.L.C. Patrick Heron, a member of our board of directors, is one of the managing members of FHMLS X, L.L.C.

### **2021 convertible promissory note financing**

In August 2021, we entered into a note purchase agreement with certain investors (the Note Purchase Agreement), pursuant to which in August 2021 we issued and sold to such investors the August 2021 Notes, in the aggregate principal amount of approximately \$139.5 million. The August 2021 Notes accrue interest at a rate of 6% per annum and become payable upon demand of the holders of at least a majority of the outstanding principal amount of the August 2021 Notes, including FLS X, one year from the date of issuance, subject to earlier conversion or repayment in the event we complete an equity financing or a change of control. We have not paid any interest on the August 2021 Notes to date. The participants in this August 2021 Note financing included the following 5% or greater stockholders and or entities affiliated with members of our board of directors.

	<b>Aggregate principal amount of notes</b>
<b>Participants</b>	
Frazier Life Sciences X, L.P.(1)	\$ 35,772,111
Deerfield Private Design Fund V, L.P.(2)	\$ 15,000,000
Entities affiliated with Lightspeed Venture Partners(3)	\$ 10,000,000

(1) Includes (i) approximately \$2.3 million of principal amount and accrued interest from the YamadaCo Notes, the North Bridge Notes and the March 2020 HilleVax Note, which converted into approximately \$4.5 million principal amount of August 2021 Notes, (ii) approximately \$6.3 million of principal amount and accrued interest from the April 2021 HilleVax Notes and the July 2021 HilleVax Note and (iii) \$25.0 million of principal amount issued for cash consideration. Additional details regarding FLS X and its equity holdings are provided under the section titled "Principal stockholders." Patrick Heron, a member of our board of directors, is one of the managing members of FHMLS X, L.L.C, which is an affiliate of FLS X.

(2) Elise Wang, a member of our board of directors, was a Partner at the Public Structured Finance group at Deerfield at the time of our August 2021 convertible promissory note financing.

(3) Represents notes acquired by Lightspeed Venture Partners Select IV, L.P., Lightspeed Frontier I-M L.P., Lightspeed Frontier I-E L.P. and Lightspeed Frontier I-N L.P. Shelley Chu, a member of our board of directors, was a Partner at Lightspeed Venture Partners at the time of our August 2021 convertible promissory note financing.

The outstanding principal and unpaid accrued interest due on the August 2021 Notes will automatically convert into shares of our common stock immediately prior to the closing of this offering.

## **Investor rights under the Note Purchase Agreement**

### ***Registration rights***

The Note Purchase Agreement provides FLS X, Takeda, and all holders of the August 2021 Notes with specified registration rights relating to the registration of shares of common stock held by such entities, including shares of our common stock issuable upon conversion of the August 2021 Notes, shares of common stock held by FLS X and shares of our common stock (including shares issuable upon the exercise or conversion of any securities exercisable or convertible into shares of our common stock) held by Takeda.

The registration rights terminate upon the earlier of: (i) the closing of a qualified corporate transaction, as defined in the Note Purchase Agreement, (ii) five years after the closing of this offering or (iii) with respect to a particular holder, such time at which such holder can sell all shares held by it in compliance with Rule 144 under the Securities Act.

See the section titled “Description of capital stock—Registration rights” for more information regarding these registration rights.

### ***Voting rights***

The Note Purchase Agreement provides for rights relating to the election of members to serve on our board of directors. Pursuant to the Note Purchase Agreement, the following directors served as members of our board of directors and, as of the date of this prospectus, continue to so serve: Shelley Chu, M.D., Ph.D., Julie Gerberding, M.D. M.P.H., Robert Hershberg, M.D., Ph.D., Jeri Hilleman, Patrick Heron, Jaime Sepulveda, M.D., D.Sc., M.P.H., Susan Silbermann, Rajeev Venkayya, M.D. and Elise Wang. Dr. Hershberg, our Chairman, President and Chief Executive Officer, was initially selected to serve on our board of directors in his role as Chief Executive Officer. Dr. Chu, Mr. Heron, Mr. Venkayya and Ms. Wang were initially selected to serve on our board of directors as designees of Lightspeed Venture Partners Select IV, L.P., FLS X, Takeda and Deerfield Private Design Fund V, L.P., respectively.

The voting rights provisions of the Note Purchase Agreement will terminate upon the closing of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by holders of our common stock. The composition of our board of directors after this offering is described in more detail under “Management—Board composition and election of directors.”

### ***Other rights***

The Note Purchase Agreement provides certain holders of the August 2021 Notes with various additional rights including, among others, information rights, pre-emptive rights, drag along rights, rights of first refusal, co-sale rights, and certain additional covenants made by us. Except as set forth above, all rights under the Note Purchase Agreement will terminate upon the closing of this offering.

## **Takeda agreements**

### ***License agreement and clinical manufacturing and supply agreement***

On July 2, 2021, we and Takeda, one of our 5% stockholders, entered into the Takeda License and a clinical supply agreement. The Takeda License is described in “Business—Intellectual property—License agreement with Takeda.”

In connection with the Takeda License, we (i) entered into a Stock Issuance Agreement with Takeda, pursuant to which we issued Takeda 500,000 shares of our common stock, (ii) issued the Takeda Warrant to purchase 3,500,000 shares of our common stock at an exercise price of \$0.0001 per share and (iii) granted the Takeda Warrant Right, pursuant to which Takeda has a right to receive an additional common stock warrant upon the closing of this offering if Takeda's fully-diluted ownership represents less than a specified percentage of our fully-diluted capitalization, including shares issuable upon conversion of the August 2021 Notes, calculated immediately prior to the closing of this offering, each as partial consideration under the Takeda License. The Takeda Warrant expires ten years from its date of issuance, subject to its earlier termination upon the completion of certain mergers, acquisitions and similar transactions. The Takeda Warrant Right will expire upon the closing of this offering based on an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus. See the section titled "Description of capital stock—Warrants" for more information regarding the Takeda Warrant and the Takeda Warrant Right. As contemplated in connection with the entry into the Takeda License, Takeda became a party to the Note Purchase Agreement pursuant to which we provided Takeda with various investor rights, including pre-emptive rights, drag along rights, voting rights and certain registration rights. Except for the registration rights set forth above, each of the investor rights provided to Takeda will terminate upon the closing of this offering. See "—Investor rights under the Note Purchase Agreement" above for more information regarding these voting rights and registration rights.

## **Merger**

### ***Initial founder equity issuances***

On April 19, 2019, YamadaCo III issued and sold to Tadataka Yamada, M.D., a former member of our board of directors, 462,500 shares of YamadaCo III common stock at a purchase price of \$0.00105946 per share, after giving effect to the merger described below. On April 10, 2019, YamadaCo III issued and sold to FLS IX 481,377 shares of YamadaCo III common stock at a purchase price of \$0.00105946 per share, after giving effect to the merger described below. On March 31, 2020, the shares issued and sold to FLS IX were transferred to FLS X pursuant to the YamadaCo Securities Transfer Agreement.

On June 27, 2019, North Bridge V issued and sold to a family trust of which David Socks, our Chief Financial Officer and Chief Business Officer, is a trustee (the David Socks Trust), 462,500 shares of North Bridge V common stock at a purchase price of \$0.00105946 per share, after giving effect to the merger described below. On May 30, 2019, North Bridge V issued and sold to FLS IX 481,377 shares of North Bridge V common stock at a purchase price of \$0.00105946 per share, after giving effect to the merger described below. On March 31, 2020, the shares issued and sold to FLS IX were transferred to FLS X pursuant to the North Bridge Securities Transfer Agreement.

On April 1, 2020, we issued and sold to Robert Hershberg, M.D., Ph.D., our President and Chief Executive Officer and a member of our board of directors, 462,500 shares of our common stock at a purchase price of \$0.00105946 per share. On March 31, 2020, we issued and sold to FLS X 481,377 shares of our common stock at a purchase price of \$0.00105946 per share.

On February 8, 2021, we entered into stock restriction agreements with each of Dr. Hershberg, Dr. Yamada and Mr. Socks providing for vesting and a company right to repurchase the unvested shares held by Dr. Hershberg, Dr. Yamada and Mr. Socks upon the occurrence of certain events.

For more information regarding these stock issuances to Dr. Hershberg and Mr. Socks, see the section in this prospectus entitled "Executive and director compensation—Equity-based incentive awards" and "Executive and Director compensation—Narrative disclosure to summary compensation table—Director compensation."

### ***Merger agreement***

On February 8, 2021, YamadaCo III and North Bridge V merged with and into our company, with our company surviving the merger (the Merger). Immediately prior to the Merger, we effected a 943.8776-for-1 forward stock split for each outstanding share of our common stock. Effective upon the closing of the Merger, each issued and outstanding share of YamadaCo III and North Bridge V was converted into 943.8776 shares of our common stock.

### ***Additional equity issuances***

Following the Merger, on February 8, 2021, we issued and sold to FLS X 955,869 shares of our common stock at a purchase price of \$0.00105946 per share.

### **Equity grants to executive officers and directors**

We have granted restricted stock to certain of our executive officers and non-employee directors, as more fully described in the section titled “Executive and director compensation.”

### **Employment arrangements**

We have entered into employment letter agreements with our executive officers. For more information regarding these letter agreements, see the section titled “Executive and director compensation—Employment letter agreements with our executive officers.”

### **Director and officer indemnification**

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys’ fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person’s services as a director or executive officer.

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we have purchased a policy of directors’ and officers’ liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. For further information, see “Executive and director compensation—Limitations of liability and indemnification matters.”

### **Policies and procedures for related person transactions**

Our board of directors will adopt a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related-person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds the lesser of \$120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person

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[Table of Contents](#)

has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.



## Principal stockholders

The following table sets forth information with respect to the beneficial ownership of our common stock as of November 15, 2021, and as adjusted to reflect the sale of shares of common stock in this offering, by:

- our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power. Applicable percentage ownership prior to this offering is based on 5,488,000 shares of common stock outstanding on November 15, 2021, which includes 1,583,508 shares subject to forfeiture or a right of repurchase. Applicable percentage ownership after this offering is based on the sale of \_\_\_\_\_ shares of common stock in this offering and gives effect to the automatic conversion of the August 2021 Notes into an aggregate of \_\_\_\_\_ shares of our common stock immediately prior to the closing of this offering (based on an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on \_\_\_\_\_, 2021). In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of November 15, 2021 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. The table below excludes any potential purchases in this offering by the beneficial owners identified in the table below.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o HilleVax, Inc., 75 State Street, Suite 100 - #9995, Boston, Massachusetts 02109. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of beneficial owner	Beneficial ownership prior to this offering		Beneficial ownership after this offering	
	Number	Percent	Number	Percent
<b>5% or greater stockholders</b>				
Frazier Life Sciences X, L.P.(1)	2,400,000	43.7%		
Takeda Vaccines, Inc.(2)	500,000	9.1%		
Estate of Tadataka Yamada, M.D.(3)	462,500	8.4%		
<b>Named executive officers and directors</b>				
Rob Hershberg, M.D., Ph.D.(4)	462,500	8.4%		
Shelley Chu, Ph.D.	—	*		
Julie Gerberding, M.D. Ph.D.(5)	25,000	*		
Patrick Heron(2)	2,400,000	43.7%		
Jeri Hilleman(6)	25,000	*		
Jaime Sepulveda, M.D., D.Sc., MPH(7)	25,000	*		
Susan Silbermann(8)	25,000	*		
Rajeev Venkayya, M.D.	—	*		
Elise Wang	—	*		
All executive officers and directors as a group (12 persons)(9)	3,959,000	72.1%		

## Table of Contents

\* Less than 1%.

- (1) The shares are held directly by Frazier Life Sciences X, L.P. (FLS X). The general partner of FLS IX is FHMLS X, L.P., and the general partner of FHMLS X, L.P. is FHMLS X, L.L.C. James Topper, M.D., Ph.D., and Patrick Heron are the sole managing members of FHMLS X, L.L.C. and share voting and investment power of the securities held by FLS X. Dr. Topper and Mr. Heron disclaim beneficial ownership of such securities except to the extent of their pecuniary interest therein. The number of shares beneficially owned after the offering includes \_\_\_\_\_ shares of common stock issuable upon the conversion of August 2021 Notes in the aggregate principal amount of \$35.8 million plus accrued interest held by FLS X immediately prior to the closing of this offering (based on an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on \_\_\_\_\_, 2021). The address for FLS X is 601 Union Street, Suite 3200, Seattle, WA 98101.
- (2) The number of shares beneficially owned by Takeda Vaccines, Inc., an indirect wholly owned subsidiary of Takeda Pharmaceutical Company Limited, before the offering does not include 3,500,000 shares of common stock issuable upon exercise of the Takeda Warrant, which becomes exercisable upon the closing of this offering. The number of shares beneficially owned after the offering includes 3,500,000 shares of common stock issuable upon the exercise of the Takeda Warrant. The address for Takeda Vaccines, Inc. is 75 Sidney Street, Cambridge, Massachusetts 02139 and the address of Takeda Pharmaceutical Company Limited is 1-1, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo, 103-8668, Japan.
- (3) Consists of (i) 393,848 shares of common stock held in the Tadataka Yamada Estate, of which the spouse of Dr. Yamada is the executor, and (ii) 68,652 shares of common stock held by a family trust, for which the spouse of Dr. Yamada is a trustee.
- (4) Includes 267,383 shares subject to repurchase by us within 60 days after November 15, 2021.
- (5) Includes 25,000 shares subject to repurchase by us within 60 days after November 15, 2021.
- (6) Includes 25,000 shares subject to repurchase by us within 60 days after November 15, 2021.
- (7) Includes 25,000 shares subject to repurchase by us within 60 days after November 15, 2021.
- (8) Includes 25,000 shares subject to repurchase by us within 60 days after November 15, 2021.
- (9) Includes the shares described in footnotes 4 through 8 above. Also includes 457,500 shares of common stock held by David Socks, our Chief Financial Officer and Chief Business Officer, 439,000 shares of common stock held by Aditya Kohli, Ph.D., our Chief Operating Officer, and 100,000 shares held by Astrid Borkowski, M.D., Ph.D., our Chief Medical Officer. Includes 1,002,149 shares subject to repurchase by us within 60 days after November 15, 2021.

## Description of capital stock

### General

The following description summarizes some of the terms of our amended and restated certificate of incorporation and amended and restated bylaws and of the Delaware General Corporation Law. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our amended and restated certificate of incorporation, amended and restated bylaws and our investors' rights agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

Following the closing of this offering, our authorized capital stock will consist of \_\_\_\_\_ shares of common stock, \$0.0001 par value per share, and \_\_\_\_\_ shares of preferred stock, \$0.0001 par value per share.

### Common stock

As of September 30, 2021, there were 5,488,000 shares of our common stock outstanding, including 1,626,870 shares of restricted common stock which are subject to forfeiture or our right of repurchase, and held of record by 38 stockholders. Based on the number of shares of common stock outstanding as of September 30, 2021, and assuming (i) the automatic conversion of the August 2021 Notes into an aggregate of \_\_\_\_\_ shares of our common stock immediately prior to the closing of this offering (based on an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on \_\_\_\_\_, 2021) and (ii) the issuance by us of \_\_\_\_\_ shares of common stock in this offering, there will be \_\_\_\_\_ shares of common stock outstanding upon the closing of this offering. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we may issue may be entitled to elect. Subject to supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our amended and restated certificate of incorporation. See below in "—Anti-takeover effects of Delaware law and our certificate of incorporation and bylaws—Amendment of charter provisions."

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding. Holders of common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking funds provisions applicable to the common stock. All outstanding shares of common stock are, and the common stock to be outstanding upon the closing of this offering will be, duly authorized, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

## Preferred stock

As of the date of this prospectus, we do not have shares of preferred stock authorized or outstanding. Under the terms of our amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, our board of directors has the authority, without further action by our stockholders, to issue up to \_\_\_\_\_ shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the dividend, voting and other rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deterring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

## Warrants

In July 2021, in connection with the Takeda License, we issued the Takeda Warrant to purchase 3,500,000 shares of our common stock with an exercise price of \$0.0001 per share. The Takeda Warrant contains a net exercise provision under which Takeda may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares of our common stock based on the fair market value of our common stock at the time of the net exercise of the warrant after deduction of the aggregate exercise price. The Takeda Warrant becomes exercisable upon the closing of this offering and expires ten years from its date of issuance, subject to its earlier termination upon the completion of certain mergers, acquisitions and similar transactions.

In July 2021, in connection with the Takeda License, we granted to Takeda the Takeda Warrant Right, pursuant to which Takeda has a right to right to receive an additional common stock warrant should Takeda's fully-diluted ownership represent less than a certain specified percentage of our fully-diluted capitalization, including shares issuable upon conversion of the outstanding August 2021 Notes in connection with this offering, calculated immediately prior to the closing of this offering. The Takeda Warrant Right will expire upon the closing of this offering (based on an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover of this prospectus).

## Registration rights

As of September 30, 2021, upon the closing of this offering holders of \_\_\_\_\_ shares of our common stock, which includes all of the shares of common stock issuable upon the automatic conversion of the August 2021 Notes, or their transferees, will be entitled to the following rights with respect to the registration of such shares for public resale under the Securities Act, pursuant to the Note Purchase Agreement by and among us and certain investors. In addition, upon the closing of this offering Takeda will be entitled to the same rights with respect to the registration of 3,500,000 shares of our common stock underlying the Takeda Warrant. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

### ***Demand registration rights***

*Form S-1.* If at any time beginning six months following the effective date of the registration statement of which this prospectus forms a part, the holders of at least 25% of the registrable securities request in writing that we effect a registration with respect to all or a part of the registrable securities then outstanding where the price to the public of the offering is \$10.0 million or more, we may be required to provide notice to all holders of registrable securities and to use commercially reasonable efforts to effect such registration; provided, however, that we will not be required to effect such a registration if, within the preceding 12 months, we have already effected two registrations for the holders of registrable securities in response to these demand registration rights, subject to certain exceptions.

*Form S-3.* If at any time we become entitled under the Securities Act to register our shares on Form S-3, the holders of at least 20% of the registrable securities request in writing that we effect a registration with respect to all or a part of the registrable securities then outstanding where the price to the public of the offering is \$3.0 million or more, we may be required to provide notice to all holders of registrable securities and to use commercially reasonable efforts to effect such registration; provided, however, that we will not be required to effect such a registration if, within the preceding 12 months, we have already effected two registrations on Form S-3 for the holders of registrable securities.

If the holders requesting registration intend to distribute their shares by means of an underwriting, the underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

### ***Piggyback registration rights***

If at any time following the closing of this offering we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

### ***Indemnification***

The Note Purchase Agreement contains customary cross indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in a registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

### ***Expenses***

Ordinarily, other than underwriting discounts and commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling securityholders, blue sky fees and expenses and the expenses of any special audits incident to the registration.

### ***Termination of registration rights***

The registration rights terminate upon the earlier of: (i) five years after the closing of this offering or (ii) with respect to a particular holder, such time at which such holder can sell all shares held by it in compliance with Rule 144 under the Securities Act.

## **Anti-takeover effects of Delaware law and our certificate of incorporation and bylaws**

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

### ***Undesignated preferred stock***

The ability of our board of directors, without action by the stockholders, to issue up to \_\_\_\_\_ shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

### ***Stockholder meetings***

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board of directors, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

### ***Requirements for advance notification of stockholder nominations and proposals***

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

### ***Elimination of stockholder action by written consent***

Our amended and restated certificate of incorporation and amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

### ***Staggered board of directors***

Our amended and restated bylaws provides that our board of directors will be divided into three classes. The directors in each class will serve for a three-year term, with one class being elected each year by our stockholders. For more information on the classified board of directors, see "Management—Board composition and election of directors." This system of electing directors may tend to discourage a third party from attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

### ***Removal of directors***

Our amended and restated certificate of incorporation provides that no member of our board of directors may be removed from office except for cause and, in addition to any other vote required by law, upon the approval of not less than two thirds of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

### ***Stockholders not entitled to cumulative voting***

Our amended and restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

### ***Delaware anti-takeover statute***

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed to be “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

### ***Choice of forum***

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, creditors or other constituents; (iii) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our amended and restated certificate of incorporation or amended and restated bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (v) any action asserting a claim governed by the internal affairs doctrine. The 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 will also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. In any case, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. The enforceability of similar choice of forum provisions in other companies’ certificates of incorporation has been challenged in legal



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## [Table of Contents](#)

proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. Our amended and restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision.

### ***Amendment of charter provisions***

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least two thirds of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board of directors and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

### **Transfer agent and registrar**

The transfer agent and registrar for our common stock will be . The transfer agent and registrar's address is .

### **The Nasdaq Global Market listing**

We have applied to list our common stock on the Nasdaq Global Market under the symbol "HLVX."

### **Limitations of liability and indemnification matters**

For a discussion of liability and indemnification, see "Executive and director compensation—Limitations of liability and indemnification matters."

## Shares eligible for future sale

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock. Although we have applied to have our common stock listed on Nasdaq, we cannot assure you that there will be an active public market for our common stock.

Based on the number of shares of our common stock outstanding as of September 30, 2021, and assuming (i) the issuance of \_\_\_\_\_ shares in this offering, (ii) the automatic conversion of the August 2021 Notes into an aggregate of \_\_\_\_\_ shares of our common stock immediately prior to the closing of this offering (based on an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on \_\_\_\_\_, 2021), (iii) no exercise of the underwriters' option to purchase additional shares of common stock and (iv) no exercise of outstanding options, warrants or other rights, we will have outstanding an aggregate of \_\_\_\_\_ shares of common stock immediately following this offering.

Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. Shares purchased by our affiliates would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining \_\_\_\_\_ shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration, such as under Rule 144 or 701 under the Securities Act, each of which is summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below.

In addition, 3,500,000 shares of common stock issuable to Takeda upon the exercise of the Takeda Warrant will become exercisable upon the closing of this offering. Upon exercise of the Takeda Warrant, these shares of common stock will be eligible for sale subject to the lock-up agreements described below and Rules 144 and 701 under the Securities Act.

### Lock-up agreements

We, our officers, directors and holders of all or substantially all of our securities, have agreed with the underwriters that for a period of 180 days, after the date of this prospectus, subject to specified exceptions, we or they will not sell or offer to sell any shares or related securities currently or hereafter owned either of record or beneficially (as defined in Rule 13d-3 under the Exchange Act) by the holder or family member, enter into any swap, make any demand for, or exercise any right with respect to, the registration under the Securities Act of the offer and sale of any shares or related securities, or cause to be filed a registration statement, prospectus or prospectus supplement (or an amendment or supplement thereto) with respect to any such registration, or publicly announce any intention to do any of the foregoing. Upon expiration of the lock-up period, certain of our stockholders will have the right to require us to register their shares under the Securities Act. See "—Registration rights" below and "Description of capital stock—Registration rights."

J.P. Morgan Securities LLC and SVB Leerink LLC may, in their sole discretion and at any time or from time to time before the termination of the lock-up period, in certain cases without public notice, release all or any portion of the securities subject to lock-up agreements.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

## **Rule 10b5-1 trading plans**

Following the closing of this offering, certain of our officers, directors and significant stockholders may adopt written plans, known as Rule 10b5-1 trading plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis to diversify their assets and investments. Under these 10b5-1 trading plans, a broker may execute trades pursuant to parameters established by the officer, director or stockholder when entering into the plan, without further direction from such officer, director or stockholder. Such sales would not commence until the expiration of the applicable lock-up agreements entered into by such officer, director or stockholder in connection with this offering.

## **Rule 144**

### ***Affiliate resales of restricted securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in “broker’s transactions” or certain “riskless principal transactions” or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately \_\_\_\_\_ shares immediately after this offering; or
- the average weekly trading volume in our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of \$50,000, the seller must file a notice on Form 144 with the SEC and Nasdaq concurrently with either the placing of a sale order with the broker or the execution of a sale directly with a market maker.

### ***Non-affiliate resales of restricted securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

## **Rule 701**

In general, under Rule 701, any of an issuer’s employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in

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## [Table of Contents](#)

reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

### **Equity plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our equity incentive plans and employee stock purchase plan. We expect to file the registration statement covering shares offered pursuant to these stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

### **Registration rights**

Upon the closing of this offering holders of \_\_\_\_\_ shares of our common stock, which includes all of the shares of common stock issuable upon the automatic conversion of the August 2021 Notes immediately prior to the closing of this offering, will be entitled to various rights with respect to the registration of these shares under the Securities Act upon the closing of this offering. In addition, upon the closing of this offering, Takeda will be entitled to the same rights with respect to the registration of \_\_\_\_\_ shares of our common stock underlying the Takeda Warrant. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchase by our affiliates. See “Description of capital stock—Registration rights” for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.

## Material United States federal income tax consequences to non-U.S. holders

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the Code) Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the IRS), in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder’s particular circumstances, including the impact of the Medicare contribution tax on net investment income and the alternative minimum tax. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our

common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

**THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.**

### **Definition of a non-U.S. holder**

For purposes of this discussion, a “Non-U.S. Holder” is any beneficial owner of our common stock that is neither a “U.S. person” nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code), or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

### **Distributions**

As described in the section titled “Dividend policy,” we do not anticipate declaring or paying cash dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder’s adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below in “—Sale or other taxable disposition.”

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). If a Non-U.S. Holder holds the stock through a financial institution or other intermediary, the Non-U.S. Holder will be required to provide appropriate documentation to the intermediary, which then will be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder

maintains a permanent establishment or fixed base in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

### **Sale or other taxable disposition**

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment or fixed base in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest (USRPI) by reason of our status as a U.S. real property holding corporation (USRPHC) for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A Non-U.S. Holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on gain realized upon the sale or other taxable disposition of our common stock, which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of our common stock by a Non-U.S. Holder will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.



## **Information reporting and backup withholding**

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

## **Additional withholding tax on payments made to foreign accounts**

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections are commonly referred to as the Foreign Account Tax Compliance Act (FATCA)) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or subject to the proposed Treasury Regulations discussed below, gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in clause (i) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would also have applied to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers (including applicable withholding agents) generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

## Underwriting

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC and SVB Leerink LLC are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the initial public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name	Number of shares
J.P. Morgan Securities LLC	
SVB Leerink LLC	
Stifel, Nicolaus & Company, Incorporated	
Guggenheim Securities, LLC	
<b>Total</b>	

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the shares of common stock directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ per share. Any such dealers may resell shares to certain other brokers or dealers at a discount of up to \$ per share from the initial public offering price. After the initial offering of the shares to the public, if all of the shares of common stock are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of any shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to purchase up to additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is \$ per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Without option to purchase additional shares exercise	With full option to purchase additional shares exercise
Per Share	\$	\$
Total	\$	\$

## Table of Contents

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately \$ . We have agreed to reimburse the underwriters for expenses of up to \$ relating to the clearance of this offering with the Financial Industry Regulatory Authority.

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with, the Securities and Exchange Commission a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exercisable or exchangeable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, loan, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC and SVB Leerink LLC for a period of 180 days after the date of this prospectus, other than the shares of our common stock to be sold in this offering.

Our directors, executive officers and substantially all of our stockholders (collectively, the lock-up parties) have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each lock-up party, with limited exceptions, for a period of 180 days after the date of this prospectus (such period, the restricted period), may not (and may not cause any of their direct or indirect affiliates to), without the prior written consent of J.P. Morgan Securities LLC and SVB Leerink LLC, (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including, without limitation, common stock or such other securities which may be deemed to be beneficially owned by such lock-up parties in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant (collectively with the common stock, the lock-up securities)), (2) enter into any hedging, swap or other agreement or transaction that transfers, in whole or in part, any of the economic consequences of ownership of the lock-up securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of lock-up securities, in cash or otherwise, (3) make any demand for, or exercise any right with respect to, the registration of any lock-up securities, or (4) publicly disclose the intention to do any of the foregoing. Such persons or entities have further acknowledged that these undertakings preclude them from engaging in any hedging or other transactions or arrangements (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) designed or intended, or which could reasonably be expected to lead to or result in, a sale or disposition or transfer (by any person or entity, whether or not a signatory to such agreement) of any economic consequences of ownership, in whole or in part, directly or indirectly, of any lock-up securities, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of lock-up securities, in cash or otherwise.

The restrictions described in the immediately preceding paragraph and contained in the lock-up agreements between the underwriters and the lock-up parties do not apply, subject in certain cases to various conditions, to

## [Table of Contents](#)

certain transactions, including (a) transfers of lock-up securities: (i) as bona fide gifts, or for bona fide estate planning purposes, (ii) by will, other testamentary document or intestacy, (iii) to any member of the undersigned's immediate family or to trust for the direct or indirect benefit of the lock-up party or the immediate family of the lock-up party, or if the lock-up party is a trust, to a trustor or beneficiary of the trust or to the estate of a beneficiary of such trust, (iv) to a partnership, limited liability company or other entity of which the lock-up party and its immediate family members are the legal and beneficial owner of all of the outstanding equity securities or similar interests, (v) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (iv), (vi) in the case of a corporation, partnership, limited liability company, trust or other business entity, (A) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate of the lock-up party, or to any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the lock-up party or its affiliates or (B) as part of a distribution to members or stockholders of the lock-up party; (vii) by operation of law, provided that any transferee or distributee shall execute and deliver to the representatives a lock-up agreement, (viii) to us from an employee or consultant upon death, disability or termination of employment of such employee or consultant, (ix) as part of a sale of lock-up securities acquired in this offering or in open market transactions after the completion of this offering, (x) to us in connection with the vesting, settlement or exercise of restricted stock units, options, warrants or other rights to purchase shares of our common stock (including "net" or "cashless" exercise), including for the payment of exercise price and tax and remittance payments, or (xi) pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction approved by our board of directors and made to all stockholders involving a change in control, provided that if such transaction is not completed, all such lock-up securities would remain subject to the restrictions in the immediately preceding paragraph; (b) exercise of the options, settlement of RSUs or other equity awards, or the exercise of warrants granted pursuant to plans described in this prospectus, provided that any lock-up securities received upon such exercise, vesting or settlement would be subject to restrictions similar to those in the immediately preceding paragraph; (c) the conversion of outstanding convertible notes into shares of our common stock or warrants to acquire shares of our common stock, provided that any common stock or warrant received upon such conversion would be subject to restrictions similar to those in the immediately preceding paragraph; and (d) the establishment by lock-up parties of trading plans under Rule 10b5-1 under the Exchange Act, provided that such plan does not provide for the transfer of lock-up securities during the restricted period.

J.P. Morgan Securities LLC and SVB Leerink LLC, in their sole discretion, may release the securities subject to any of the lock-up agreements with the underwriters described above, in whole or in part at any time.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

We have applied to have our common stock listed on the Nasdaq Global Market under the symbol "HLVX."

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in

## Table of Contents

the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the \_\_\_\_\_, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our shares of common stock, or that the shares will trade in the public market at or above the initial public offering price.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and

other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

## **Selling restrictions**

### ***Notice to prospective investors in the European Economic Area***

In relation to each Member State of the European Economic Area, or, each a Member State, no shares have been offered or will be offered pursuant to the offering to the public in that Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and us that it is a “qualified investor” within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Member State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an “offer to the public” in relation to shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

### ***Notice to prospective investors in the United Kingdom***

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order, or, all such persons together being referred to as relevant persons, or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

## [Table of Contents](#)

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

### ***Notice to prospective investors in Canada***

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

### ***Notice to prospective investors in Switzerland***

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, us or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority, or FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

### ***Notice to prospective investors in the Dubai International Financial Centre (DIFC)***

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority (DFSA). This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this document relates may be illiquid and/or subject to



restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document you should consult an authorized financial advisor.

In relation to its use in the DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

***Notice to prospective investors in the United Arab Emirates***

The shares have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

***Notice to prospective investors in Australia***

This prospectus:

- does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (Corporations Act);
- has not been, and will not be, lodged with the Australian Securities and Investments Commission (ASIC), as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act, Exempt Investors.

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer, transfer, assign or otherwise alienate those shares to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

***Notice to prospective investors in Japan***

The shares have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the shares nor any interest therein may be offered or sold,



## [Table of Contents](#)

directly or indirectly, in Japan or to, or for the benefit of, any “resident” of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

### ***Notice to prospective investors in Hong Kong***

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or the SFO, of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, or the CO, or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the SFO and any rules made thereunder.

### ***Notice to prospective investors in Singapore***

Singapore SFA Product Classification—In connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of shares, we have determined, and hereby notify all relevant persons (as defined in Section 309A(1) of the SFA), that the shares are “prescribed capital markets products” (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Each underwriter has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each underwriter has represented and agreed that it has not offered or sold any shares or caused the shares to be made the subject of an invitation for subscription or purchase and will not offer or sell any shares or cause the shares to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, whether directly or indirectly, to any person in Singapore other than:

- (a) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA;
- (b) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA and in accordance with the conditions specified in Section 275 of the SFA; or
- (c) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

## Table of Contents

- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:
- (i) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 276(4)(i)(B) of the SFA;
  - (ii) where no consideration is or will be given for the transfer;
  - (iii) where the transfer is by operation of law;
  - (iv) as specified in Section 276(7) of the SFA; or
  - (v) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

### ***Notice to prospective investors in Bermuda***

Shares may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

### ***Notice to prospective investors in Saudi Arabia***

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority, or the CMA, pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended, or the CMA Regulations. The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorized financial adviser.

### ***Notice to prospective investors in the British Virgin Islands***

The shares are not being, and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on behalf of us. The shares may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands), or BVI Companies, but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands.

### ***Notice to prospective investors in China***

This prospectus will not be circulated or distributed in the PRC and the shares will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

***Notice to prospective investors in Korea***

The shares have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea, or the FSCMA, and the decrees and regulations thereunder and the shares have been and will be offered in Korea as a private placement under the FSCMA. None of the shares may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea, or the FETL, and the decrees and regulations thereunder. The shares have not been listed on any of securities exchanges in the world including, without limitation, the Korea Exchange in Korea. Furthermore, the purchaser of the shares shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares. By the purchase of the shares, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares pursuant to the applicable laws and regulations of Korea.

***Notice to prospective investors in Taiwan***

The shares have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares in Taiwan.

***Notice to prospective investors in South Africa***

Due to restrictions under the securities laws of South Africa, no “offer to the public” (as such term is defined in the South African Companies Act, No. 71 of 2008 (as amended or re-enacted), or the South African Companies Act, is being made in connection with the issue of the shares in South Africa. Accordingly, this document does not, nor is it intended to, constitute a “registered prospectus” (as that term is defined in the South African Companies Act) prepared and registered under the South African Companies Act and has not been approved by, and/or filed with, the South African Companies and Intellectual Property Commission or any other regulatory authority in South Africa. The shares are not offered, and the offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions stipulated in section 96 (1) applies:

- Section 96 (1) (a)      the offer, transfer, sale, renunciation or delivery is to:
- (i)    persons whose ordinary business, or part of whose ordinary business, is to deal in securities, as principal or agent;
  - (ii)   the South African Public Investment Corporation;
  - (iii) persons or entities regulated by the Reserve Bank of South Africa;
  - (iv)   authorized financial service providers under South African law;
  - (v)   financial institutions recognized as such under South African law;
  - (vi)   a wholly-owned subsidiary of any person or entity contemplated in (c), (d) or (e), acting as agent in the capacity of an authorized portfolio manager for a pension fund, or as manager for a collective investment scheme (in each case duly registered as such under South African law); or
  - (vii) any combination of the person in (i) to (vi); or

## Table of Contents

Section 96 (1) (b) the total contemplated acquisition cost of the securities, for any single addressee acting as principal is equal to or greater than ZAR1,000,000 or such higher amount as may be promulgated by notice in the Government Gazette of South Africa pursuant to section 96(2)(a) of the South African Companies Act.

Information made available in this prospectus should not be considered as “advice” as defined in the South African Financial Advisory and Intermediary Services Act, 2002.

### ***Notice to prospective investors in Israel***

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares of common stock is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and “qualified individuals,” each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

## Legal matters

The validity of the shares of common stock offered hereby will be passed upon for us by Latham & Watkins LLP. The underwriters are being represented by Davis Polk & Wardwell, Menlo Park, California.

## Experts

Ernst & Young LLP, independent registered public accounting firm, has audited our combined financial statements at December 31, 2019 and 2020 and for the period from January 8, 2019 (inception) to December 31, 2019 and the year ended December 31, 2020, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about HilleVax, Inc.'s ability to continue as a going concern as described in Note 1 to the combined financial statements). We have included our combined financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

## Where you can find more information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. Upon the closing of this offering, we will be required to file periodic reports, proxy statements and other information with the SEC pursuant to the Exchange Act. The SEC maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that site is [www.sec.gov](http://www.sec.gov).

Upon the closing of this offering, we will become subject to the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, will file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information will be available at the website of the SEC referred to above. We maintain a website at [www.hillevax.com](http://www.hillevax.com). Upon the closing of this offering, you may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website address does not constitute incorporation by reference of the information contained on our website, and you should not consider the contents of our website in making an investment decision with respect to our common stock.

HilleVax, Inc.

Index to Combined Financial Statements

	<u>Page</u>
<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-2
<a href="#">Combined Balance Sheets</a>	F-3
<a href="#">Combined Statements of Operations</a>	F-4
<a href="#">Combined Statements of Stockholders' Deficit</a>	F-5
<a href="#">Combined Statements of Cash Flows</a>	F-6
<a href="#">Notes to Combined Financial Statements</a>	F-7

## 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 combined balance sheets of HilleVax, Inc. (the Company) as of December 31, 2019 and 2020, the related combined statements of operations, stockholders' deficit and cash flows for the period from January 8, 2019 (inception) to December 31, 2019 and the year ended December 31, 2020, and the related notes (collectively referred to as the "combined financial statements"). In our opinion, the combined financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2020, and the results of its operations and its cash flows for the period from January 8, 2019 (inception) to December 31, 2019 and the year ended December 31, 2020 in conformity with U.S. generally accepted accounting principles.

### The Company's Ability to Continue as a Going Concern

The accompanying combined financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, has a working capital deficiency, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The combined financial statements do not include any adjustments that might result from the outcome of these uncertainties.

### 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 and in accordance with auditing standards generally accepted in the United States of America. 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 audit, 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  
October 19, 2021

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

	<u>December 31,</u>		<u>September 30,</u>
	<u>2019</u>	<u>2020</u>	<u>2021</u>
			(unaudited)
<b>Assets</b>			
Current assets:			
Cash	\$ 403	\$ 457	\$ 129,579
Prepaid expenses and other current assets (includes related party amounts of \$30, \$48 and \$1, respectively)	48	48	49
<b>Total current assets</b>	<b>451</b>	<b>505</b>	<b>129,628</b>
Property and equipment, net	—	—	14
Operating lease right-of-use assets	—	—	193
Other assets	—	—	332
<b>Total assets</b>	<b><u>\$ 451</u></b>	<b><u>\$ 505</u></b>	<b><u>\$ 130,167</u></b>
<b>Liabilities and Stockholders' Deficit</b>			
Current liabilities:			
Accounts payable (includes related party amounts of \$202, \$130 and \$41, respectively)	\$ 202	\$ 130	\$ 1,225
Accrued expenses	5	100	941
Accrued interest (includes related party amounts of \$9, \$24 and \$182, respectively)	9	24	711
Convertible promissory notes payable at fair value (includes related party amounts of (\$906, \$3,024 and \$35,757, respectively)	906	3,024	139,464
Current portion of operating lease liability	—	—	31
Warrant liabilities	—	—	51,132
<b>Total current liabilities</b>	<b>1,122</b>	<b>3,278</b>	<b>193,504</b>
Operating lease liability, net of current portion	—	—	159
Other long-term liabilities	—	—	1
<b>Total liabilities</b>	<b>1,122</b>	<b>3,278</b>	<b>193,664</b>
Commitments and contingencies (Note 3)			
Stockholders' deficit:			
Common stock, \$0.0001 par value; authorized shares—10,000,000 at December 31, 2019 and 2020 and September 30, 2021 (unaudited); issued shares—1,887,754, 2,831,631 and 5,488,000 at December 31, 2019, 2020 and September 30, 2021 (unaudited), respectively; outstanding shares—1,887,754, 2,831,631 and 3,861,130 at December 31, 2019 and 2020 and September 30, 2021 (unaudited), respectively	—	—	—
Additional paid-in capital	2	3	4,360
Accumulated deficit	(673)	(2,776)	(67,857)
<b>Total stockholders' deficit</b>	<b>(671)</b>	<b>(2,773)</b>	<b>(63,497)</b>
<b>Total liabilities and stockholders' deficit</b>	<b><u>\$ 451</u></b>	<b><u>\$ 505</u></b>	<b><u>\$ 130,167</u></b>

See accompanying notes.



**HilleVax, Inc.**  
**Combined Statements of Operations**  
(in thousands, except share and per share data)

	Period from January 8, 2019 (inception) to December 31, 2019	Year Ended December 31, 2020	Nine Months Ended September 30,	
			2020	2021 (unaudited)
<b>Operating expenses:</b>				
Research and development (includes related party amounts of \$0, \$0, \$0 and \$15, respectively)	\$ —	\$ —	\$ —	\$ 1,623
In-process research and development	—	—	—	37,666
General and administrative (includes related party amounts of \$424, \$467, \$361 and \$599, respectively)	\$ 633	\$ 1,295	850	3,064
<b>Total operating expenses</b>	<u>633</u>	<u>1,295</u>	<u>850</u>	<u>42,353</u>
Loss from operations	(633)	(1,295)	(850)	(42,353)
<b>Other income (expense):</b>				
Interest expense (includes related party amounts of \$(9), \$(29), \$(21) and \$(199), respectively)	(9)	(29)	(21)	(734)
Change in fair value of convertible promissory notes (includes related party amounts of \$(31), \$(779), \$(513) and \$(1,435), respectively)	(31)	(779)	(513)	(1,392)
Change in fair value of warrant liabilities	—	—	—	(20,598)
Other income (expense)	—	—	—	(4)
<b>Total other income (expense)</b>	<u>(40)</u>	<u>(808)</u>	<u>(534)</u>	<u>(22,728)</u>
<b>Net loss</b>	<u>\$ (673)</u>	<u>\$ (2,103)</u>	<u>\$ (1,384)</u>	<u>\$ (65,081)</u>
Net loss per share, basic and diluted	<u>\$ (0.55)</u>	<u>\$ (0.81)</u>	<u>\$ (0.55)</u>	<u>\$ (20.62)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>1,223,006</u>	<u>2,598,266</u>	<u>2,519,910</u>	<u>3,156,879</u>

See accompanying notes.

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Combined balance at January 8, 2019 (inception)	—	\$ —	\$ —	\$ —	\$ —
Issuance of common stock to founders	1,887,754	—	2	—	2
Net loss	—	—	—	(673)	(673)
Combined balance at December 31, 2019	1,887,754	—	2	(673)	(671)
Issuance of common stock to founders	943,877	—	1	—	1
Net loss	—	—	—	(2,103)	(2,103)
Combined balance at December 31, 2020	2,831,631	—	3	(2,776)	(2,773)
Issuance of common stock (unaudited)	955,869	—	1	—	1
Issuance of common stock in connection with license agreement (unaudited)	500,000	—	4,357	—	4,357
Vesting restrictions placed on previously issued and outstanding common stock (unaudited)	(1,387,500)	—	(1)	—	(1)
Vesting of restricted shares (unaudited)	961,130	—	—	—	—
Net loss (unaudited)	—	—	—	(65,081)	(65,081)
Combined balance at September 30, 2021 (unaudited)	<u>3,861,130</u>	<u>\$ —</u>	<u>\$ 4,360</u>	<u>\$ (67,857)</u>	<u>\$ (63,497)</u>

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Combined balance at December 31, 2019	1,887,754	\$ —	\$ 2	\$ (673)	\$ (671)
Issuance of common stock to founders (unaudited)	943,877	—	1	—	1
Net loss (unaudited)	—	—	—	(1,384)	(1,384)
Combined balance at September 30, 2020 (unaudited)	<u>2,831,631</u>	<u>\$ —</u>	<u>\$ 3</u>	<u>\$ (2,057)</u>	<u>\$ (2,054)</u>

See accompanying notes.

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

	Period from January 8, 2019 (inception) to December 31, 2019	Year Ended December 31, 2020	Nine Months Ended September 30,	
			2020	2021 (unaudited)
<b>Cash flows from operating activities</b>				
Net loss	\$ (673)	\$ (2,103)	\$(1,384)	\$ (65,081)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	—	—	—	1
Change in fair value of convertible promissory notes (includes related party amounts of \$31, \$779, \$513 and \$1,435, respectively)	31	779	513	1,392
Change in fair value of warrant liabilities	—	—	—	20,598
Acquired in-process research and development	—	—	—	37,666
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets (includes related party amounts of \$(30), \$(18), \$3 and \$47, respectively)	(48)	—	21	(24)
Accounts payable and accrued expenses (includes related party amounts of \$202, \$(72), \$(144) and \$(89), respectively)	207	23	(130)	1,616
Accrued interest (includes related party amounts of \$9, \$29, \$21 and \$205, respectively)	9	29	21	734
Operating lease right-of-use assets and liabilities	—	—	—	(3)
Net cash used in operating activities	<u>(474)</u>	<u>(1,272)</u>	<u>(959)</u>	<u>(3,101)</u>
<b>Cash flows from investing activities</b>				
Cash paid for purchased in-process research and development	—	—	—	(2,763)
Purchase of property and equipment	—	—	—	(15)
Net cash used in investing activities	<u>—</u>	<u>—</u>	<u>—</u>	<u>(2,778)</u>
<b>Cash flows from financing activities</b>				
Proceeds from issuance of common stock	2	1	1	1
Proceeds from issuance of convertible promissory notes	875	1,325	1,025	135,000
Net cash provided by financing activities	<u>877</u>	<u>1,326</u>	<u>1,026</u>	<u>135,001</u>
Net increase in cash	403	54	67	129,122
Cash—beginning of period	—	403	403	457
Cash—end of period	<u>\$ 403</u>	<u>\$ 457</u>	<u>\$ 470</u>	<u>\$ 129,579</u>
<b>Supplemental disclosure of noncash investing and financing activities</b>				
Exchange of convertible promissory notes	<u>\$ —</u>	<u>\$ 14</u>	<u>\$ 14</u>	<u>\$ 47</u>
Operating lease	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 180</u>
Issuance of Takeda Warrants in connection with Takeda License	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 30,534</u>
Issuance of common stock in connection with Takeda License	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 4,357</u>
Unpaid initial public offering costs	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 309</u>

See accompanying notes.

HilleVax, Inc.

Notes to Combined Financial Statements

(Information as of September 30, 2021 and thereafter and for the nine months ended September 30, 2020 and 2021 is unaudited)

**1. Organization, Basis of Presentation and Summary of Significant Accounting Policies**

**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 Delaware corporations formed in 2019, with HilleVax being the surviving entity (the "Merger"). The Company is a biopharmaceutical company focused on developing and commercializing novel vaccines.

**Stock Split and Conversion**

During 2019, both North Bridge V and YamadaCo III issued 1,000 shares of common stock to their founders at a purchase price of \$1.00 per share and had no other capital transactions prior to the Merger. During March and April 2020, MokshaCo issued an aggregate of 1,000 shares of common stock to its founders at a purchase price of \$1.00 per share, and had no other capital transactions prior to the Merger. Immediately prior to the Merger, the Company effected a 943.8776-for-1 forward stock split for each outstanding share of its common stock and, effective upon the closing of the Merger, each issued and outstanding share of North Bridge V and YamadaCo III was converted into 943.8776 shares of the Company's common stock. Upon completion of the Merger, the founders of each of MokshaCo, North Bridge V and YamadaCo III held an equal number of shares of common stock of the Company. The accompanying combined financial statements and notes to the combined financial statements give retroactive effect to the forward stock split and conversion for all periods presented.

**Basis of Presentation**

The Company's combined financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The accompanying combined financial statements include the accounts of the Company (the receiving entity), North Bridge V and YamadaCo III prior to the Merger. The Company, North Bridge V and YamadaCo III were entities under the common control of Frazier Life Sciences X, L.P. or its affiliates ("Frazier") as a result of, among others, Frazier's: (i) ownership of a majority of the outstanding capital stock of each of the combined companies, (ii) financing of each of the combined companies, (iii) control of board of directors of each of the combined companies, and (iv) management of each of the combined companies. All of the combined 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 combined financial statements report the financial position, results of operations and cash flows of the combined companies prior to the Merger. The combined financial statements also include, subsequent to its formation in May 2021, the accounts of HilleVax GmbH, a wholly-owned subsidiary formed in Zurich, Switzerland. All intercompany transactions have been eliminated in combination.

**Liquidity and Capital Resources**

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 (see Note 3), preparing for its planned 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

HilleVax, Inc.

**Notes to Combined Financial Statements - (Continued)**  
**(Information as of September 30, 2021 and thereafter and for the nine months ended**  
**September 30, 2020 and 2021 is unaudited)**

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 September 30, 2021, the Company has funded its operations through the issuance of convertible promissory notes.

The accompanying combined financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty. 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 has prepared cash flow forecasts which indicate that based on the Company's expected operating losses, negative cash flows and maturities of outstanding convertible promissory notes, there is substantial doubt about the Company's ability to continue as a going concern for twelve months after the date the combined financial statements for the year ended December 31, 2020 and the nine months ended September 30, 2021 were issued.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional funding. Management intends to raise additional capital through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, the Company may not be able to secure additional financing in a timely manner or on favorable terms, if at all. Furthermore, if the Company issues equity securities to raise additional funds, its existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of the Company's existing stockholders. If the Company raises additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to its potential products on terms that are not favorable to the Company. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce or eliminate its research and development programs or other operations. If any of these events occur, the Company's ability to achieve the development and commercialization goals would be adversely affected.

***Use of Estimates***

The preparation of the Company's combined 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 combined financial statements and accompanying notes. The most significant estimates in the Company's combined financial statements relate to accruals for research and development expenses, and 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.

***Unaudited Interim Financial Information***

The accompanying interim combined balance sheet as of September 30, 2021, the combined statements of operations, statements of stockholders' deficit and statements of cash flows for the nine months ended

HilleVax, Inc.

**Notes to Combined Financial Statements - (Continued)**  
**(Information as of September 30, 2021 and thereafter and for the nine months ended**  
**September 30, 2020 and 2021 is unaudited)**

September 30, 2020 and 2021 and the related footnote disclosures are unaudited. In management's opinion, the unaudited interim financial statements have been prepared on the same basis as the audited combined financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of September 30, 2021 and its results of operations and cash flows for the nine months ended September 30, 2020 and 2021 in accordance with GAAP. The results for the nine months ended September 30, 2021 are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

**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 September 30, 2021. In accordance with ASC 825, the Company records these convertible promissory notes at fair value with changes in fair value recorded in the combined 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 earnings 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.

The carrying amounts of the Company's financial instruments, including cash classified within the Level 1 designation discussed above, prepaid and other current assets, accounts payable, and accrued liabilities, approximate fair value due to their short maturities. Warrant liabilities and convertible notes are recorded at fair value on a recurring basis.

The Company has no financial assets measured at fair value on a recurring basis. 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.

HilleVax, Inc.

**Notes to Combined Financial Statements - (Continued)**  
**(Information as of September 30, 2021 and thereafter and for the nine months ended**  
**September 30, 2020 and 2021 is unaudited)**

Liabilities measured at fair value on a recurring basis are as follows (in thousands):

	Total	Fair Value Measurements at Reporting Date Using:		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of December 31, 2019:				
Frazier Notes	\$ 906	\$ —	\$ —	\$ 906
As of December 31, 2020:				
Frazier Notes	\$ 3,024	\$ —	\$ —	\$ 3,024
As of September 30, 2021:				
Warrant liabilities	\$ 51,132	\$ —	\$ —	\$ 51,132
Convertible promissory notes	139,464	—	—	139,464
Total	\$ 190,596	\$ —	\$ —	\$ 190,596

The warrant liabilities consist of an issued and outstanding common stock warrant (the “Takeda Warrant”) and a right to receive an additional common stock warrant (the “Takeda Warrant Right”, and together with the Takeda Warrant, the “Takeda Warrants”) issued to Takeda Vaccines, Inc. (“Takeda”) in connection with a July 2021 license agreement (see Note 3). The Takeda Warrants are accounted for as liabilities as they do not meet 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 the Company’s own stock. The fair value of the Takeda Warrants is derived from the model used to estimate the fair value the Company’s common stock (see Note 5).

As further described in Note 4, the Company issued convertible promissory notes to Frazier (the “Frazier Notes”) from April 2019 to July 2021 and issued unsecured convertible promissory notes in August 2021 (the “August 2021 Notes”) to investors including Frazier. The Company has elected the fair value option for each of its convertible promissory note issuances due to certain embedded features within the notes. The fair value of the Frazier Notes and the August 2021 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 Frazier Notes were exchanged for August 2021 Notes in August 2021.

The Company adjusts the carrying value of its warrant liabilities and convertible promissory notes to their estimated fair value at each reporting date, with any related increases or decreases in the fair value recorded as change in fair value of warrant liabilities and as change in fair value of convertible promissory notes, respectively, in the combined statements of operations.

The following table summarizes information about the significant unobservable inputs used in the fair value measurements for the convertible promissory notes as of December 31, 2019:

Liability	Key unobservable inputs	Range
Frazier Notes	Estimated time to liquidity	1.8 years
	Discount rate	21.4%

HilleVax, Inc.

**Notes to Combined Financial Statements - (Continued)**  
**(Information as of September 30, 2021 and thereafter and for the nine months ended**  
**September 30, 2020 and 2021 is unaudited)**

The following table summarizes information about the significant unobservable inputs used in the fair value measurements for the convertible promissory notes as of December 31, 2020:

Liability	Key unobservable inputs	Range
Frazier Notes	Estimated time to liquidity	1.0 - 1.3 years
	Volatility	90.0%
	Discount rate	21.4%

The following table summarizes information about the significant unobservable inputs used in the fair value measurements for the Takeda Warrants and the August 2021 Notes as of September 30, 2021:

Liability	Key unobservable inputs	Range
Takeda Warrants	Transaction prices per share	\$21.10 - \$22.31
	Estimated time to liquidity	0.29 - 2.0 years
	Discount rate	10%
August 2021 Notes	Estimated time to liquidity	0.29 - 2.0 years
	Volatility	80 - 100%
	Discount rate	18%
	Risk-free interest rate	0.3% - 0.5%

There are significant judgments, assumptions and estimates inherent in the determination of the fair value of each of the instruments described above. These include determination of a valuation method and selection of the possible outcomes available to the Company, including the determination of timing and expected future investment returns for such scenarios. The related judgments, assumptions and estimates are highly interrelated and changes in any one assumption could necessitate changes in another. In particular, any changes in the probability of a particular outcome would require a related change to the probability of another outcome. In the future, depending on the valuation approaches used and the expected timing and weighting of each, the inputs described above, or other inputs, may have a greater or lesser impact on the Company's estimates of fair value.

The following table provides a reconciliation of all liabilities measured at fair value using Level 3 significant unobservable inputs (in thousands):

	Warrant Liabilities	Convertible Promissory Notes
Balance at January 8, 2019 (inception)	\$ —	\$ —
Issuance of convertible promissory notes	—	875
Change in fair value	—	31
Balance at December 31, 2019	—	906
Issuance of convertible promissory notes	—	1,325
Exchange of convertible promissory notes	—	14
Change in fair value	—	779
Balance at December 31, 2020	—	3,024
Issuance of convertible promissory notes	—	145,772
Exchange of convertible promissory notes (excluding accrued interest) (Note 4)	—	(10,724)
Issuance of warrants	30,534	—
Change in fair value	20,598	1,392
Balance at September 30, 2021	<u>\$ 51,132</u>	<u>\$ 139,464</u>



HilleVax, Inc.

**Notes to Combined Financial Statements - (Continued)**  
**(Information as of September 30, 2021 and thereafter and for the nine months ended**  
**September 30, 2020 and 2021 is unaudited)**

**Cash**

The Company considers all highly liquid investments with original maturities of three months or less when purchased to be cash equivalents. The Company had no cash equivalents for any of the periods presented. Cash includes cash in readily available checking accounts.

**Concentrations of Credit Risk**

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of 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 (generally 3 years). Repairs and maintenance costs are charged to expense as incurred.

**Deferred Offering Costs**

The Company has deferred offering costs consisting of legal, accounting and other fees and costs directly attributable to its planned IPO. The deferred offering costs will be offset against the proceeds received upon the completion of the planned IPO. In the event the planned IPO is terminated, all of the deferred offering costs will be expensed within the Company's statements of operations. As of September 30, 2021, \$0.3 million of deferred offering costs were recorded within other assets on the combined balance sheet. No such costs were included on the combined balance sheet as of December 31, 2020.

**Leases**

The Company adopted Accounting Standards Update ("ASU") No. 2016-02, *Leases* ("Topic 842"), as of January 8, 2019 (inception). Under ASC 842, 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 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. 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.

HilleVax, Inc.

**Notes to Combined Financial Statements - (Continued)**  
**(Information as of September 30, 2021 and thereafter and for the nine months ended**  
**September 30, 2020 and 2021 is unaudited)**

***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 September 30, 2021.

***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 planned 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 or accrued liabilities. 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 recognized over the requisite service period of the awards (generally the vesting period) on a straight-line basis. The Company recognizes forfeitures as they occur.

HilleVax, Inc.

**Notes to Combined Financial Statements - (Continued)**  
**(Information as of September 30, 2021 and thereafter and for the nine months ended**  
**September 30, 2020 and 2021 is unaudited)**

***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 combined 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 combined statements of operations. Any accrued interest and penalties are included within the related tax liability in the combined 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. The Company's comprehensive loss was the same as its reported net loss for all periods presented.

***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 combined net loss by the combined 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 1,605,652 shares from the weighted-average

HilleVax, Inc.

**Notes to Combined Financial Statements - (Continued)**  
**(Information as of September 30, 2021 and thereafter and for the nine months ended  
September 30, 2020 and 2021 is unaudited)**

number of common shares outstanding for the nine months ended September 30, 2021. No shares of common stock were unvested during the year ended December 31, 2020 or prior. Diluted net loss per share is computed by dividing the combined 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 warrants and convertible promissory notes. 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 unvested common stock, common stock warrants and convertible debt would be antidilutive.

***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 Pronouncements***

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which eliminates, modifies and adds disclosure requirements on fair value measurements. The Company adopted the new guidance at its inception and the adoption had no material effect on the Company’s combined financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by removing certain exceptions to the general principles in ASC 740 and also improves consistent application by clarifying and amending existing guidance. The Company adopted the new guidance at its inception and the adoption had no material impact on the Company’s combined financial statements and related disclosures.

***Recently Issued Accounting Pronouncements***

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity’s own equity. Specifically, the new guidance simplifies accounting for the issuance of convertible instruments by removing certain separation models required under existing guidance. In addition, the ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and amends the diluted earnings-per-share (“EPS”) calculation guidance in certain areas to improve the consistency of EPS calculations. ASU No. 2020-06 is effective for fiscal years beginning after December 15, 2023, with early adoption permitted for fiscal years beginning after December 15, 2020. The Company does not currently expect the adoption of this guidance will have an impact on its combined financial statements and related disclosures.

HilleVax, Inc.

**Notes to Combined Financial Statements - (Continued)**  
**(Information as of September 30, 2021 and thereafter and for the nine months ended**  
**September 30, 2020 and 2021 is unaudited)**

**2. Related Party Transactions**

Frazier is a principal stockholder of the Company and is represented on the Company's board of directors. From January 8, 2019 (inception) to September 30, 2021, 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, 2019 and 2020 and September 30, 2021, the Company had outstanding amounts due from Frazier of \$16,000, \$14,000 and \$1,000, respectively, related to these shared operating expenses. As of December 31, 2019 and 2020 and September 30, 2021, the Company had outstanding amounts due to Frazier of \$0.2 million, \$0.1 million and \$41,000, respectively, related to these shared operating expenses. For the period from January 8, 2019 (inception) to December 31, 2019, the year ended December 31, 2020 and the nine months ended September 30, 2020 and 2021, the Company incurred \$0.5 million, \$0.5 million, \$0.4 million and \$0.6 million, respectively, of shared operating expenses. In addition to the shared operating expenses, the Company issued convertible promissory notes to Frazier during 2019, 2020 and 2021 (see Note 4).

Mountain Field LLC ("Mountain Field") is an entity owned by a former member of the Company's board of directors. From January 8, 2019 (inception) to September 30, 2021, the Company charged Mountain Field for various personnel related and other administrative expenses associated with the operations of Mountain Field. These shared expenses were allocated based on time incurred by personnel. As of December 31, 2019, 2020 and September 30, 2021, the Company had amounts due from Mountain Field of \$14,000, \$34,000 and \$0, respectively, related to shared operating expenses. For the period from January 8, 2019 (inception) to December 31, 2019, the year ended December 31, 2020 and the nine months ended September 30, 2020 and 2021, the Company charged to (was charged by) Mountain Field \$0.1 million, \$43,000, \$9,000 and \$(4,000), respectively, for shared expenses.

**3. Commitments and Contingencies**

**License Agreement**

On July 2, 2021, the Company entered into a license agreement with Takeda Vaccines, Inc. ("Takeda") pursuant to which it was granted an exclusive sublicensable, royalty-bearing license (the "Takeda License") to 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 500,000 shares of its common stock at a fair value of \$4.4 million, (iii) issued Takeda a warrant (the "Takeda Warrant") to purchase 3,500,000 shares of its common stock at an exercise price of \$0.0001 per share that expires on July 2, 2031 and becomes exercisable upon certain change of control transactions of the Company or the consummation of an initial public offering ("IPO") by the Company, at an initial fair value of \$30.5 million, 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,

HilleVax, Inc.

**Notes to Combined Financial Statements - (Continued)**  
**(Information as of September 30, 2021 and thereafter and for the nine months ended**  
**September 30, 2020 and 2021 is unaudited)**

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, \$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.

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. The \$37.7 million fair value (including \$0.3 million of transaction costs) of the consideration paid for these research and development assets, which have no alternative future use, was recorded as in-process research and development in the Company's combined statement of operations for the nine months ended September 30, 2021.

**Operating Lease**

In August 2021, the Company entered into a five-year noncancelable operating lease for a facility in Switzerland. 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.

As of September 30, 2021, the remaining lease term of the Company's operating lease was 60 months, and the discount rate on the Company's operating lease was 6.0%. As there was not an implicit rate within the lease, the discount rate was determined by using a set of peer companies incremental borrowing rates. For the nine months ended September 30, 2021, operating lease expense and cash paid for amounts included in the measurement of lease liabilities were immaterial.

## HilleVax, Inc.

**Notes to Combined Financial Statements - (Continued)**  
**(Information as of September 30, 2021 and thereafter and for the nine months ended**  
**September 30, 2020 and 2021 is unaudited)**

Future minimum noncancelable operating lease payments, which commenced in October 2021, are as follows (in thousands):

	September 30, 2021
Years ending December 31:	
2021 (remaining)	\$ 11
2022	44
2023	44
2024	44
2025	44
Thereafter	35
Total undiscounted operating lease payments	222
Present value adjustment	(32)
Operating lease liability	190
Less current portion of operating lease liability	31
Operating lease liability, net of current portion	<u>\$ 159</u>

**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.

**4. Convertible Promissory Notes*****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 combined statements of operations. In March 2020, \$14,000 of accrued interest on the 2019 Frazier Notes was converted to principal upon the transfer of those convertible promissory notes between Frazier entities, and the maturity dates of the Frazier Notes were extended to March 2021. 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 \$139.52 million of August 2021 Notes. 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



HilleVax, Inc.

**Notes to Combined Financial Statements - (Continued)**  
**(Information as of September 30, 2021 and thereafter and for the nine months ended**  
**September 30, 2020 and 2021 is unaudited)**

outstanding principal and accrued interest on the Frazier Notes. The August 2021 Notes bear interest at a rate of 6% per annum, compounded annually. The August 2021 Notes become payable upon demand of the holders of at least a majority of the outstanding principal, including Frazier (the "Requisite Holders"), on August 31, 2022 (the "Maturity Date"), and become due and payable on August 31, 2024, subject to earlier conversion or repayment in the event the Company completes certain equity financings or a change of control. The August 2021 Notes can be converted/redeemed as follows (i) automatically converted into qualified equity financing shares upon a qualified equity financing, with a conversion price of the lesser of 80% of the price paid per share in such financing or the conversion cap price per share, (ii) optionally converted by election of the Requisite Holders into non-qualified equity financing shares upon a non-qualified equity financing with a conversion price of 80% of the price paid per share in such financing, (iii) optionally converted into common stock any time after the Maturity Date, with a conversion price per share of the conversion cap price per share, (iv) automatically converted into common stock upon a qualified IPO with a conversion price per share of the lesser of 80% of the IPO price per share, or the conversion cap price per share, (v) upon certain corporate transactions, receive cash equal to the greater of (A) two times the then outstanding principal and accrued interest and (B) an amount equal to the amount that would be received as if the August 2021 Notes were converted into common stock with a conversion price of the conversion cap price per share, and (vi) automatically converted into common stock upon a qualified SPAC, with a conversion price of the lesser of 80% of the common stock price implied by the nominal value of the Company in such financing or the conversion cap price per share. The conversion cap price per share is defined as \$500.0 million less the outstanding principal and accrued interest divided by the total of (1) the total number of common shares outstanding immediately prior to conversion, (2) the number of common shares issuable upon exercise or conversion of exercisable or convertible securities, and (3) the number of shares of capital stock reserved for issuance under the Company's equity incentive plan.

The note purchase agreement includes, among others, covenants related to delivery of certain financial reports, certain registration rights, voting provisions regarding the composition of the Company's board of directors, and limitations on the Company's ability to pay dividends, incur additional indebtedness or consummate certain changes of control. The note purchase agreement also contains customary events of default, including bankruptcy, the failure to make payments when due, and certain material adverse changes. Upon the occurrence of an event of default, subject to any specified cure periods, all amounts owed by the Company may be declared immediately due and payable.

For the period from January 8, 2019 (inception) to December 31, 2019, the year ended December 31, 2020 and the nine months ended September 30, 2020 and 2021, the Company recognized \$31,000, \$0.8 million \$0.5 million and \$1.4 million, respectively, of change in fair value of convertible promissory notes in the combined statements of operations. For the period from January 8, 2019 (inception) to December 31, 2019, the year ended December 31, 2020 and the nine months ended September 30, 2020 and 2021, the Company recognized \$9,000, \$29,000 \$21,000 and \$0.7 million, respectively, of interest expense in connection with outstanding convertible promissory notes. As of December 31, 2019 and 2020 and September 30, 2021, the outstanding principal balance on convertible promissory notes was \$0.9 million, \$2.2 million and \$139.5 million, respectively.



HilleVax, Inc.

**Notes to Combined Financial Statements - (Continued)**  
**(Information as of September 30, 2021 and thereafter and for the nine months ended**  
**September 30, 2020 and 2021 is unaudited)**

**5. Stockholders' Deficit**

**Common Stock**

As of December 31, 2019 and 2020 and September 30, 2021, the Company was authorized to issue 10,000,000 shares of voting common stock, of which 1,877,754 shares, 2,831,631 shares and 5,488,000 shares, respectively, were issued.

On February 8, 2021, subsequent to the Merger, the Company issued and sold 955,869 shares of common stock to Frazier at \$0.00105946 per share.

On February 8, 2021, certain of the Company's founders entered into stock restriction agreements granting the Company a repurchase right on 1,387,500 shares of fully vested common stock originally purchased in 2019 and 2020. The Company has the right, but not the obligation, to repurchase unvested shares in the event the founder's relationship with the Company is terminated, subject to certain limitations, at \$0.00064139 per share. The repurchase right lapsed for 346,875 shares on the effective date of the stock restriction agreements and the repurchase right for the remaining 1,040,625 shares lapses in equal monthly amounts over the following 48-month period ending in February 2025.

From March through May 2021, the Company issued and sold an aggregate of 421,000 shares of restricted common stock outside of the 2021 Plan (defined and described below) at a purchase price of \$0.00105946 per share to certain employees and consultants. The Company has the right, but not the obligation, to repurchase unvested shares at the original purchase price in the event the purchaser's relationship with the Company is terminated, subject to certain limitations. The repurchase rights lapse over a four-year period, with 25% lapsing on the first anniversary of the vesting commencement date and the remaining portion lapsing in 36 equal monthly amounts thereafter.

**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. A total of 2,212,500 shares of common stock were initially reserved for issuance under the 2021 Plan, which amount was subsequently decreased to 1,766,500 shares in a series of amendments through July 2, 2021.

From February through April 2021, the Company issued 1,019,500 shares of restricted common stock to certain of its employees, consultants and directors under the 2021 Plan. The shares are subject to forfeiture restrictions under which the shares would become immediately retired in the event the stockholder's service with the Company is terminated. The share restriction generally lapses over a four-year period, with 25% lapsing on the first anniversary of the vesting commencement date and the remaining portion lapsing in 36 equal monthly amounts thereafter.

In March 2021, the Company issued and sold an aggregate of 10,000 shares of restricted common stock under the 2021 Plan at a purchase price of \$0.00105946 per share to certain consultants. The Company has the right, but not the obligation, to repurchase unvested shares at the original purchase price in the event the purchaser's relationship with the Company is terminated, subject to certain limitations. The repurchase rights lapse on the first anniversary of the vesting commencement date.

## HilleVax, Inc.

**Notes to Combined Financial Statements - (Continued)**  
**(Information as of September 30, 2021 and thereafter and for the nine months ended**  
**September 30, 2020 and 2021 is unaudited)**

A summary of the Company's unvested shares is as follows:

	<b>Number of Unvested Shares</b>
Balance at December 31, 2020	—
Vesting restrictions placed on previously issued shares	1,387,500
Sale of unvested common stock	431,000
Issuance of unvested restricted stock awards	1,019,500
Forfeited shares	(100,000)
Repurchased shares	(150,000)
Share vesting	(961,130)
Balance at September 30, 2021	<u>1,626,870</u>

For accounting purposes, unvested shares of common stock are considered issued, but not outstanding until they vest. As of September 30, 2021, the Company has no material repurchase liability related to the unvested shares described above and paid the original purchase price for the shares it repurchased.

**Valuation of Common Stock and Stock-Based Compensation Expense**

Prior to obtaining the Takeda License on July 2, 2021, the fair value of the Company's common stock was nominal since the Company was not sufficiently capitalized and held no assets that could be used to generate future revenues. Subsequent to obtaining the Takeda License, the Company estimated the fair value of its common stock using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide: Valuation of Privately Held Company Equity Securities Issued as Compensation (the "Practice Aid"). The Practice Aid prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. The Company's 2021 valuations utilized a scenario-based analysis that estimated the fair value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the Company, including various IPO, stay private and dissolution scenarios, and applying a discount for lack of marketability for certain equity holders. The Company considered various stay private scenarios using the income approach and allocated the indicated equity value, adjusted for the expected impact of the convertible notes, to each class of equity on a fully-diluted basis, considering option value for certain option classes. The Company also considered various IPO scenarios based on expected equity values in an IPO and allocated the indicated equity value to each class of equity on a fully-diluted basis considering the dilutive impacts of the convertible notes.

Since all equity awards from inception to September 30, 2021 were issued prior to obtaining the Takeda License on July 2, 2021, the Company has recorded no material stock-based compensation expense through September 30, 2021 and has no material unrecognized stock-based compensation as of September 30, 2021.

HilleVax, Inc.

**Notes to Combined Financial Statements - (Continued)**  
**(Information as of September 30, 2021 and thereafter and for the nine months ended**  
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**Common Stock Reserved for Future Issuance**

Common stock reserved for future issuance consists of the following:

	September 30, 2021
Common stock warrants	3,500,000
Shares available for issuance under the 2021 Plan	837,000
	<u>4,337,000</u>

As of December 31, 2019 and 2020, no shares of common stock were reserved for future issuance.

**6. 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):

	Period from January 8, 2019 (inception) to December 31, 2019	Year Ended December 31, 2020
Tax computed at federal statutory rate	\$ (141)	\$ (442)
Convertible debt	8	170
Permanent differences and other	2	4
Change in valuation allowance	131	268
Provision for income taxes	<u>\$ —</u>	<u>\$ —</u>

Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31,	
	2019	2020
Deferred tax assets:		
Start up and organization costs	\$ 131	\$ 398
Net operating loss carryforwards	—	1
Total deferred tax assets	131	399
Valuation allowance	(131)	(399)
Deferred tax assets, net of allowance	<u>\$ —</u>	<u>\$ —</u>

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 assets are realizable, the valuation allowance will be reduced. The Company has recorded a full valuation allowance of \$0.4 million as of December 31, 2020 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.

HilleVax, Inc.

**Notes to Combined Financial Statements - (Continued)**  
**(Information as of September 30, 2021 and thereafter and for the nine months ended**  
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As of December 31, 2020, the Company has federal net operating loss carryforwards of approximately \$3,000. As a result of the Tax Cuts and Jobs Act of 2017, for U.S. 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.

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.

Uncertain tax positions are evaluated based upon the facts and circumstances that exist at each reporting period. Subsequent changes in judgment based upon new information may lead to changes in recognition, derecognition, and measurement. Adjustment may result, for example, upon resolution of an issue with the taxing authorities or expiration of a statute of limitations barring an assessment for an issue. As of December 31, 2020, the Company has no uncertain tax positions.

The Company files income tax returns in the United States and Switzerland. The Company's tax returns from inception through December 31, 2020 remain open and subject to examination. The Company is not currently under examination by any federal, state, local or foreign tax authority.

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 combined statements of operations since inception.

## **7. Subsequent Events**

The Company has completed an evaluation of all subsequent events through October 19, 2021, the date the 2020 audited combined financial statements were available to be issued, to ensure these 2020 financial statements include appropriate disclosure of events both recognized in the 2020 financial statements and events which occurred but were not recognized in the 2020 financial statements. Except as described herein, there were no subsequent events related to the 2020 audited financial statements which required disclosure through October 19, 2021. The Company has further evaluated subsequent events related to the unaudited interim financial statements for disclosure purposes through November 23, 2021, all of which are unaudited. The Company has concluded that no subsequent event has occurred that requires disclosure.

**shares**



***Common stock***

# **Preliminary prospectus**

**J.P. Morgan**

**SVB Leerink**

**Stifel**

**Guggenheim Securities**

, 2022

## Part II

### Information not required in prospectus

#### **Item 13. Other expenses of issuance and distribution.**

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the SEC registration fee, the Financial Industry Regulatory Authority, Inc. (FINRA) filing fee and the Nasdaq Global Market listing fee.

	<b>Amount paid or to be paid</b>
SEC registration fee	\$ *
FINRA filing fee	*
Nasdaq Global Market listing fee	*
Accountants' fees and expenses	*
Legal fees and expenses	*
Transfer agent's fees and expenses	*
Printing and engraving expenses	*
Miscellaneous	*
<b>Total expenses</b>	<b>\$ *</b>

\* To be provided by amendment.

#### **Item 14. Indemnification of directors and officers.**

Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our certificate of incorporation provides that no director of the Registrant shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of

## Table of Contents

all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an Indemnitee), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our amended and restated certificate of incorporation provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act, against certain liabilities.

**Item 15. Recent sales of unregistered securities.**

Set forth below is information regarding unregistered securities issued by us since January 8, 2019. Also included is the consideration received by us for such securities and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

(a) Issuances of Securities

1. From April 2019 to October 2020, YamadaCo III, Inc. issued convertible promissory notes (YamadaCo Notes), in an aggregate principal amount of approximately \$1.3 million to Frazer Life Sciences IX, L.P. (FLS IX) (part of which were subsequently transferred to Frazier Life Sciences X, L.P. (FLS X) in March 2020) and FLS X. From May 2019 to August 2020, North Bridge V, Inc. issued convertible promissory notes (North Bridge Notes), in an aggregate principal amount of approximately \$0.4 million to FLS IX (part of which were subsequently transferred to FLS X in March 2020) and FLS X). In March 2020, we (originally as MokshaCo, Inc.) issued a convertible promissory note (MokshaCo Note), in a principal amount of \$0.5 million to FLS X. From April 2021 to July 2021, we issued convertible promissory notes (HilleVax Notes), in an aggregate principal amount of approximately \$6.3 million to FLS X. On August 31, 2021, (i) the YamadaCo Notes, the North Bridge Notes and the MokshaCo Note were cancelled in exchange for newly issued convertible promissory notes in the principal amount of approximately \$4.5 million, which amount represented the as converted principal and accrued interest on the such notes as of such date and (ii) the HilleVax Notes were cancelled in exchange for newly issued convertible promissory notes in the principal amount of approximately \$6.3 million, which amount represented the principal and accrued interest on the such notes as of such date.
2. In March and April 2020, we (originally as MokshaCo, Inc.) issued an aggregate of 1,000 shares of our common stock to our founders and entities affiliated with them at a purchase price of \$1.00 per share pursuant to stock purchase agreements. In February 2021, we effected a 943.8776-for-1 forward stock split for each outstanding share of our common stock, resulting in 943,877 shares of our common stock held by such founders and entities affiliated with them.
3. From May 2019 to June 2019, North Bridge V, Inc. issued an aggregate of 1,000 shares of its common stock to its founders and entities affiliated with them at a purchase price of \$1.00 per share pursuant to stock purchase agreements. In February 2021, effective upon the completion of the merger of North Bridge V and YamadaCo III with and into us, each issued and outstanding share of North Bridge V was converted into 943.8776 shares of our common stock, resulting in 943,877 shares of our common stock held by such founders and entities affiliated with them.
4. In April 2019, YamadaCo III, Inc. issued an aggregate of 1,000 shares of its common stock to its founders and entities affiliated with them at a purchase price of \$1.00 per share pursuant to stock purchase agreements. In February 2021, effective upon the completion of the merger of North Bridge V and YamadaCo III with and into us, each issued and outstanding share of YamadaCo III was converted into 943.8776 shares of our common stock, resulting in 943,8776 shares of our common stock held by such founders and entities affiliated with them.
5. In February 2021, we issued 955,869 shares of common stock to FLS X at a purchase price of \$0.00105946 per share pursuant to a stock purchase agreement.
6. In March, April and May 2021 we issued an aggregate of 421,000 shares of restricted common stock to certain of our employees and consultants at a purchase price of \$0.00010596 per share pursuant to stock purchase agreements.



## Table of Contents

7. In July 2021, we issued 500,000 shares of common stock to Takeda pursuant to a stock issuance agreement and a warrant to purchase 3,500,000 shares of our common stock with an exercise price of \$0.0001 per share as partial consideration for the Takeda License.
8. In August 2021, we issued convertible promissory notes in an aggregate principal amount of \$139.5 million to FLS X and other investors pursuant to a note purchase agreement, including the exchange of the YamadaCo Notes, the North Bridge Notes, the MokshaCo Note and the HilleVax Notes referenced above.

No underwriters were involved in the foregoing issuances of securities. The securities described in this section (a) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All holders of securities described above represented to us in connection with their purchase or issuance that they were accredited investors and were acquiring the securities for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The holders received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

### (b) Grants of Restricted Stock

1. In February 2021, we granted 727,500 shares of our restricted common stock under our existing 2021 equity incentive plan to certain of our employees and consultants in connection with services provided to us by such persons, 100,000 of which have been cancelled through the effective date of this registration statement.
2. In March 2021, we granted 196,000 shares of our restricted common stock under our existing 2021 equity incentive plan to certain of our employees, consultants and directors in connection with services provided to us by such persons.
3. In April 2021, we granted 106,000 shares of our restricted common stock under our existing 2021 equity incentive plan to certain of our employees, consultants and directors in connection with services provided to us by such persons.

The restricted stock as described in this section (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with our employees and directors, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of capital stock described in this Item 15 included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

**Item 16. Exhibits and financial statement schedules.**

- (c) *Exhibits.* See Exhibit Index attached to this registration statement, which is incorporated by reference herein.
- (d) *Financial statement schedules.* Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

**Item 17. Undertakings.**

The undersigned registrant hereby undertakes to provide to the underwriters, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

## Exhibit index

Exhibit Number	Description of Exhibit
1.1*	Form of Underwriting Agreement
2.1**	Agreement of Merger, dated as of February 8, 2021, by and among the Registrant, YamadaCo III, Inc. and North Bridge V, Inc.
3.1**	Certificate of Incorporation, as amended (currently in effect)
3.2**	Bylaws (currently in effect)
3.3*	Form of Amended and Restated Certificate of Incorporation (to be effective immediately prior to the closing of this offering)
3.4*	Form of Amended and Restated Bylaws (to be effective immediately prior to the closing of this offering)
4.1*	Specimen stock certificate evidencing the shares of common stock
4.2**	Warrant to purchase shares of common stock issued to Takeda Vaccines, Inc., dated July 2, 2021
4.3**	Note Purchase Agreement, dated August 31, 2021, by and among the Registrant and the other parties party thereto
5.1*	Opinion of Latham & Watkins LLP
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
10.2#**	HilleVax, Inc. 2022 Incentive Award Plan and form of stock option agreement and form of restricted stock unit agreement thereunder
10.3#**	HilleVax, Inc. 2022 Employee Stock Purchase Plan
10.4#**	Non-Employee Director Compensation Program
10.5#**	Employment Letter Agreement, dated February 8, 2021, by and between Robert Hershberg and the Registrant
10.6#**	Amended and Restated Employment Letter Agreement, dated March 1, 2021, by and between Aditya Kohli and the Registrant
10.7#**	Amended and Restated Employment Letter Agreement, dated March 1, 2021, by and between David Socks and the Registrant
10.8#**	Employment Letter Agreement, dated May 1, 2021, by and between Astrid Borkowski and the Registrant
10.11#**	Form of Indemnification Agreement for Directors and Officers
10.12†**	License Agreement, dated July 2, 2021, by and between Takeda Vaccines, Inc. and the Registrant
23.1*	Consent of independent registered public accounting firm
23.2*	Consent of Latham & Watkins LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included on signature page)

\* To be filed by amendment.

\*\* Previously submitted.

# Indicates management contract or compensatory plan.

† Portions of this exhibit have been omitted in compliance with Regulation S-K Item(b)(10)(iv).

## Signatures

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, State of Massachusetts, on this \_\_\_\_\_ day of \_\_\_\_\_, 2021.

HILLEVAX, INC.

By: \_\_\_\_\_  
Robert Hershberg, M.D., Ph.D.  
Chairman, President and Chief Executive Officer

## Signatures and power of attorney

We, the undersigned officers and directors of HilleVax, Inc., hereby severally constitute and appoint Rob Hershberg, M.D., Ph.D. and David Socks, and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him and in his name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement (or any other registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), as amended, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities held on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ Rob Hershberg, M.D., Ph.D.	Chairman, President and Chief Executive Officer (principal executive officer)	, 2021
_____ David Socks	Chief Financial Officer and Chief Business Officer (principal financial and accounting officer)	, 2021
_____ Shelley Chu, M.D., Ph.D.	Director	, 2021
_____ Julie Gerberding, M.D. M.P.H.	Director	, 2021
_____ Patrick Heron	Director	, 2021
_____ Jeryl Hilleman	Director	, 2021

[Table of Contents](#)

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>Jaime Sepulveda, M.D., D.Sc., M.P.H.</u>	Director	, 2021
<u>Susan Silbermann</u>	Director	, 2021
<u>Rajeev Venkayya, M.D.</u>	Director	, 2021
<u>Elise Wang</u>	Director	, 2021