UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-41365

HILLEVAX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**85-0545060**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
75 State Street, Suite 100 - #9995 Boston, Massachusetts	**02109**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

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

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

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

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

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

As of May 31, 2022, the registrant had 33,427,209 shares of common stock, $0.0001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 111,252	$ 124,566
Prepaid expenses and other current assets	480	141
Total current assets	111,732	124,707
Property and equipment, net	—	42
Operating lease right-of-use assets	176	189
Other assets	2,788	2,221
Total assets	$ 114,696	$ 127,159
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable (includes related party amounts of $1,301 and $22, respectively)	$ 4,010	$ 1,024
Accrued expenses (includes related party amounts of $230 and $4,911, respectively)	4,778	9,164
Accrued interest (includes related party amounts of $1,252 and $723, respectively)	4,885	2,821
Convertible promissory notes payable at fair value (includes related party amounts of $44,958 and $40,580, respectively)	175,349	158,276
Current portion of operating lease liability	35	32
Warrant liabilities - related party	93,869	56,445
Total current liabilities	282,926	227,762
Operating lease liability, net of current portion	141	153
Other long-term liabilities	1	1
Total liabilities	283,068	227,916
Commitments and contingencies (Note 3)		
Stockholders' deficit:		
Common stock, $0.0001 par value; authorized shares 50,000,000 at March 31, 2022 and December 31, 2021; issued shares—9,225,321 at March 31, 2022 and December 31, 2021, respectively; outstanding shares—6,897,450 and 6,599,886 at March 31, 2022 and December 31, 2021, respectively	1	1
Additional paid-in capital	4,698	4,426
Accumulated deficit	(173,071)	(105,184)
Total stockholders' deficit	(168,372)	(100,757)
Total liabilities and stockholders' deficit	$ 114,696	$ 127,159

See accompanying notes.

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

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development (includes related party amounts of $1,422 and $15, respectively)	$ 6,211	$ 267
In-process research and development	2,500	—
General and administrative (includes related party amounts of $26 and $165, respectively)	2,603	1,198
Total operating expenses	11,314	1,465
Loss from operations	(11,314)	(1,465)
Other income (expense):		
Interest income	6	—
Interest expense (includes related party amounts of $529 and $9, respectively)	(2,064)	(9)
Change in fair value of convertible promissory notes (includes related party amounts of $4,378 and $73, respectively)	(17,073)	(73)
Change in fair value of warrant liabilities - related party	(37,424)	—
Other income (expense)	(18)	1
Total other income (expense)	(56,573)	(81)
Net loss	$ (67,887)	$ (1,546)
Net loss per share, basic and diluted	$ (10.06)	$ (0.32)
Weighted-average shares of common stock outstanding, basic and diluted	6,748,668	4,802,907

See accompanying notes.

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at December 31, 2021	6,599,886	$ 1	$ 4,426	$ (105,184)	$ (100,757)
Vesting of restricted shares	297,564	—	—	—	—
Stock–based compensation	—	—	272	—	272
Net loss	—	—	—	(67,887)	(67,887)
Balance at March 31, 2022	6,897,450	$ 1	$ 4,698	$ (173,071)	$ (168,372)
Balance at December 31, 2020	4,759,968	$ —	$ 3	$ (2,776)	$ (2,773)
Issuance of common stock	1,606,815	—	—	—	—
Vesting restrictions placed on previously issued and outstanding common stock	(2,332,386)	—	(1)	—	(1)
Vesting of restricted shares	826,052	—	—	—	—
Net loss	—	—	—	(1,546)	(1,546)
Balance at March 31, 2021	4,860,449	$ —	$ 2	$ (4,322)	$ (4,320)

See accompanying notes.

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

	Three Months Ended March 31,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (67,887)	$ (1,546)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	272	—
Change in fair value of convertible promissory notes (includes related party amounts of $4,378 and $73, respectively)	17,073	73
Change in fair value of warrant liabilities - related party	37,424	—
Acquired in-process research and development	2,500	—
Loss on disposal of property and equipment	42	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets (includes related party amounts of $0 and $12, respectively)	(339)	10
Accounts payable and accrued expenses (includes related party amounts of $(3,402) and $67, respectively)	(1,868)	1,037
Accrued interest (includes related party amounts of $529 and $9, respectively)	2,064	9
Operating lease right-of-use assets and liabilities	4	—
Net cash used in operating activities	(10,715)	(417)
Cash flows from investing activities		
Cash paid for purchased in-process research and development	(2,500)	—
Net cash used in investing activities	(2,500)	—
Cash flows from financing activities		
Payment of initial public offering costs	(99)	—
Net cash used in financing activities	(99)	—
Net decrease in cash and cash equivalents	(13,314)	(417)
Cash and cash equivalents—beginning of period	124,566	457
Cash and cash equivalents—end of period	$ 111,252	$ 40
Supplemental disclosure of noncash investing and financing activities		
Unpaid initial public offering costs	$ 548	$ —

See accompanying notes.

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

Forward Stock Split

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

Basis of Presentation

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 companies, (ii) financing of each of the companies, (iii) control of board of directors of each of the companies, and (iv) management of each of the companies. As the merged entities were under common control, the financial statements prior to the Merger report the financial position, results of operations and cash flows of these merged companies. The financial statements also include, subsequent to its formation in May 2021, the accounts of HilleVax GmbH, a wholly-owned subsidiary formed in Zurich, Switzerland. The functional currency of both the Company and HilleVax GmbH is the U.S. dollar. The Company’s assets and liabilities that are not denominated in the functional currency are remeasured into U.S. dollars at foreign currency exchange rates in effect at the balance sheet date except for nonmonetary assets, which are remeasured at historical foreign currency exchange rates in effect at the date of transaction. Net realized and unrealized gains and losses from foreign currency transactions and remeasurement are reported in other income (expense), in the condensed consolidated statements of operations and were not material for the periods presented. All intercompany transactions have been eliminated in consolidation.

Liquidity and Capital Resources

From inception to March 31, 2022, the Company has devoted substantially all of its efforts to organizing and staffing the Company, business planning, raising capital, in-licensing its initial vaccine candidate, HIL-214, preparing for 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 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 March 31, 2022, the Company has funded its operations through the issuance of convertible promissory notes.

The accompanying condensed consolidated 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 believes that it has sufficient working capital on hand, including the net proceeds from the Company’s initial public offering ("IPO") in May 2022 (see Note 6), to fund operations through at least the next twelve months from the date these financial statements were issued. There can be no assurance that the Company will be successful in acquiring additional funding, if needed,

that the Company's projections of its future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years.

Unaudited Interim Financial Information

The unaudited condensed consolidated financial statements as of March 31, 2022, and for the three months ended March 31, 2022 and 2021, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC"), and with U.S. generally accepted accounting principles ("GAAP") applicable to interim financial statements. These unaudited condensed consolidated financial statements have been prepared on the same basis as the Company's audited financial statements and include all adjustments, consisting of only normal recurring accruals, which in the opinion of management are necessary to present fairly the Company's financial position as of the interim date and results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year or future periods. The condensed consolidated balance sheet data as of December 31, 2021 was derived from the Company's audited financial statements but does not include all disclosures required by GAAP. These unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2021, included in the Company's prospectus filed with the SEC on April 29, 2022 pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

Use of Estimates

The preparation of the Company's unaudited condensed consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's condensed consolidated financial statements and accompanying notes. The most significant estimates in the Company's unaudited condensed consolidated 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.

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 December 31, 2021. In accordance with ASC 825, the Company records these convertible promissory notes at fair value with changes in fair value recorded in the condensed consolidated statements of operations. As a result of applying the fair value option, direct costs and fees related to the convertible promissory notes were recognized in 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 and cash equivalents 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.

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

		Fair Value Measurements at Reporting Date Using:		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of March 31, 2022:				
Warrant liabilities	$ 93,869	$ —	$ —	$ 93,869
Convertible promissory notes	175,349	—	—	175,349
Total	$ 269,218	$ —	$ —	$ 269,218
As of December 31, 2021:				
Warrant liabilities	$ 56,445	$ —	$ —	$ 56,445
Convertible promissory notes	158,276	—	—	158,276
Total	$ 214,721	$ —	$ —	$ 214,721

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. 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 of the Company's common stock (see Note 5).

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 condensed consolidated statements of operations.

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 March 31, 2022:

Liability	Key Unobservable Inputs	Range
Takeda Warrants	Transaction prices per share	$9.66 - $18.62
	Estimated time to liquidity	0.12 - 1.50 years
	Discount rate	18%
August 2021 Notes	Estimated time to liquidity	0.12 - 1.50 years
	Volatility	79% - 110%
	Discount rate	16% - 18%
	Risk-free interest rate	0.2% - 2.0%

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 December 31, 2021:

Liability	Key Unobservable Inputs	Range
Takeda Warrants	Transaction prices per share	$11.83 - $12.54
	Estimated time to liquidity	0.20 - 1.75 years
	Discount rate	20%
August 2021 Notes	Estimated time to liquidity	0.20 - 1.75 years
	Volatility	80% - 100%
	Discount rate	19% - 20%
	Risk-free interest rate	0.1% - 0.7%

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 December 31, 2021	$ 56,445	$ 158,276
Change in fair value	37,424	17,073
Balance at March 31, 2022	$ 93,869	$ 175,349

Cash and Cash Equivalents

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

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. 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. As of March 31, 2022 and December 31, 2021, respectively, $2.8 million and $2.2 million of deferred offering costs were recorded within other assets on the condensed consolidated balance sheets.

Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. Lease terms are determined at the commencement date by considering whether renewal options and termination options are reasonably assured of exercise. For its long-term operating leases, the Company recognizes a lease liability and a right-of-use ("ROU") asset on its balance sheet and recognizes lease expense on a straight-line basis over the lease term. The lease liability is determined as the present value of future lease payments 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.

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 March 31, 2022.

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. 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.

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 condensed consolidated statements of operations in the period that includes the enactment date.

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

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

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. 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 consolidated net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. The Company has excluded weighted-average unvested shares of 2,476,653 shares and 1,663,801 shares, respectively, from the weighted-average number of common shares outstanding for the three months ended March 31, 2022 and 2021. Diluted net loss per share is computed by dividing the consolidated net loss by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. Potentially dilutive common stock equivalents are comprised of unvested common stock, common stock options, 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 options, 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 Standards

There were no recently adopted accounting standards which would have a material impact on the Company's financial statements.

Recently Issued Accounting Pronouncements

The Company assesses the adoption impacts of recently issued accounting standards by the Financial Accounting Standards Board or other standard setting bodies on the Company's condensed consolidated financial statements as well as material updates to previous assessments, if any. There were no new material accounting standards issued in the first quarter of 2022 that impacted the Company.

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 March 31, 2022, 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 March 31, 2022 and December 31, 2021, the Company had outstanding amounts due to Frazier of $0 and $22,000, respectively, related to these shared operating expenses. For the three months ended March 31, 2022 and 2021, the Company incurred $26,000 and $0.2 million, respectively, of shared operating expenses.

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 March 31, 2022, 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. For the three months ended March 31, 2022 and 2021, the Company charged Mountain Field $0 and $5,000, respectively, for shared expenses.

On July 2, 2021, the Company entered into a license agreement with Takeda pursuant to which it was granted an exclusive sublicensable, royalty-bearing license (the "Takeda License") to commercialize HIL-214 pharmaceutical products for all human uses on a worldwide basis outside of Japan. In connection with the Takeda License, Takeda became a related party stockholder with representation on the Company's board of directors. In March 2022, the Company paid Takeda an aggregate $2.5 million contingent payment upon the release of certain drug products and the completion of certain regulatory activities, which have no alternative future use, and was recorded as in-process research and development in the Company's condensed consolidated statement of operations for the three months ended March 31, 2022.

The Company and Takeda are party to a Transitional Services Agreement ("TSA") under which the Company is obligated to pay Takeda for certain services, including pass-through costs, related to research and development and regulatory assistance services, oversight and management of ongoing clinical and research studies, and maintenance of third party vendor contracts. For the three months ended March 31, 2022, the Company incurred $1.4 million of research and development expenses for Takeda's services. As of March 31, 2022, the Company had $1.3 million and $0.2 million, respectively, of accounts payable and accrued expenses due to Takeda. As of December 31, 2021, the Company had $4.9 million of accrued expenses due to Takeda.

3. Commitments and Contingencies

Operating Lease

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

As of March 31, 2022, the remaining lease term of the Company's operating lease was 54 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 three months ended March 31, 2022, operating lease expense and cash paid for amounts included in the measurement of lease liabilities were immaterial.

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

	March 31, 2022
Years ending December 31:	
2022 (remaining 9 months)	$ 33
2023	44
2024	44
2025	44
2026	35
Total undiscounted operating lease payments	200
Present value adjustment	(24)
Operating lease liability	176
Less current portion of operating lease liability	35
Operating lease liability, net of current portion	$ 141

In March 2022, the Company entered into a lease for office and laboratory space located in Boston, Massachusetts (the "Boston Lease"). The initial lease term is 10 years commencing upon the earlier of (i) nine months following the date the Company gains possession of the premises to commence construction of certain tenant improvements and (ii) the date certain tenant improvements are substantially completed. As of March 31, 2022, the Boston Lease had not yet commenced. Escalating base rental payments and additional charges for operating expenses and management fees are due on a monthly basis. The Boston Lease includes certain tenant improvement allowances, an option for the Company to extend the lease for a period of five years and requires a security deposit of $1.6 million. The future noncancelable lease payments related to the Boston Lease, excluding operating expenses and management fees, total $37.4 million.

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 condensed consolidated statements of operations. The Frazier Notes were exchanged for convertible promissory notes newly issued in connection with the August 2021 convertible note financing described below. For the three months ended March 31, 2021, the Company recognized a $0.1 million change in fair value of convertible promissory notes and recognized $9,000 of interest expense in connection with outstanding Frazier Notes.

August 2021 Convertible Note Financing

On August 31, 2021, the Company entered into a note purchase agreement under which it issued the August 2021 Notes for an aggregate of $139.52 million. Of the August 2021 Notes, $103.75 million were issued to new investors, $25.0 million were issued to Frazier for cash and $10.77 million were issued to Frazier in exchange for the then outstanding principal and accrued interest on the Frazier Notes. The August 2021 Notes bear interest at a rate of 6% per annum, compounded annually. For the three months ended March 31, 2022, the Company recognized a $17.1 million change in fair value of convertible promissory notes in the condensed consolidated statements of operations and recognized $2.1 million of interest expense in connection with outstanding August 2021 Notes. As of March 31, 2022 and December 31, 2021, the outstanding principal balance of the August 2021 Notes was $139.5 million.

5. Stockholders' Deficit

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

	Number of Unvested Shares
Balance at December 31, 2021	2,625,435
Share vesting	(297,564)
Balance at March 31, 2022	2,327,871

For accounting purposes, unvested shares of common stock are considered issued, but not outstanding until they vest. As of March 31, 2022 and December 31, 2021, the Company had no material repurchase liability related to the unvested shares in the table above.

2021 Equity Incentive Plan

On February 8, 2021, the Company's board of directors and stockholders approved and adopted the HilleVax, Inc. 2021 Equity Incentive Plan (the "2021 Plan"). The term of the 2021 Plan is ten years from the adoption date. Under the 2021 Plan, the Company may grant stock options, restricted stock, restricted stock units, and other stock-based awards to employees, directors or consultants of the Company and its subsidiaries. The stock options granted under the plan generally vest over a four-year period from the vesting commencement date. As of March 31, 2022 a total of 2,969,486 shares were reserved for issuance under the 2021 Plan.

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 and 2022 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 restricted stock awards from inception were issued prior to obtaining the Takeda License on July 2, 2021, the Company has recorded no material stock-based compensation expense and has no material unrecognized stock-based compensation related to these awards.

A summary of the Company's stock option activity under the 2021 Plan is as follows (in thousands, except share and per share data):

	Number of Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance at December 31, 2021	727,873	$ 6.99	9.94	$ 765
Granted	479,085	8.05		
Cancelled	(16,810)	6.99		
Balance at March 31, 2022	1,190,148	$ 7.42	9.80	$ 7,907
Vested and expected to vest at March 31, 2022	1,190,148	$ 7.42	9.80	$ 7,907
Exercisable at March 31, 2022	—	$ —	—	$ —

Stock-Based Compensation Expense

The assumptions used in the Black-Scholes option pricing model to determine the fair value of stock option grants were as follows:

	Three Months Ended March 31,	
	2022	2021 [1]
Risk-free interest rate	1.9%–2.5%	— %
Expected volatility	88.1%–89.5%	— %
Expected term (in years)	5.5–6.1	—
Expected dividend yield	0 %	0 %

[1] No stock options were granted until December 2021.

Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities similar to the expected term of the awards.

Expected volatility. Since the Company is not yet a public company and does not have a trading history for its common stock, the expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Expected term. The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historical exercise behavior, it determines the expected life assumption using the simplified method, for employees, which is an average of the contractual term of the option and its vesting period.

Expected dividend yield. The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends and, therefore, used an expected dividend yield of zero.

Stock-based compensation expense has been reported in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 201	$ —
General and administrative	71	—
Total	$ 272	$ —

The weighted average grant date fair value per share of option grants for the three months ended March 31, 2022 was $5.92. There were no option grants during the three months ended March 31, 2021. No stock options were exercised during the three months ended March 31, 2022 or 2021. As of March 31, 2022, total unrecognized stock-based compensation cost was approximately $6.0 million, which is expected to be recognized over a remaining weighted-average period of approximately 3.75 years.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following:

	March 31, 2022
Common stock warrants	5,883,500
Common stock options outstanding	1,190,148
Shares available for issuance under the 2021 Plan	216,849
	7,290,497

6. Subsequent Events

Term Loan Facility

On April 18, 2022, the Company entered into a Loan and Security Agreement ("Loan Agreement") with Hercules Capital, Inc. ("Hercules"), as administrative and collateral agent, and the lenders party thereto, providing for term loans ("Term Loans") of up to $75.0 million in the aggregate. The Company borrowed $5.0 million on April 18, 2022 and has the right to borrow up to an additional $10.0 million through December 15, 2022 and up to an additional $15.0 million through June 30, 2023 (collectively, "Term Loan 1"). The Company also has the right to borrow up to $20.0 million through June 30, 2023 ("Term Loan 2"). In addition, the Company has the right to borrow $25.0 million through March 31, 2024 ("Term Loan 3"), provided that on or prior to March 31, 2023, (i) the Company has announced that the planned Phase 2b clinical trial evaluating the safety, immunogenicity, and efficacy of HIL-214 in infants ("HIL-214 Vaccine Trial") will continue without material adverse modification after completion of the planned interim safety and immunogenicity analysis on the first 200 evaluable subjects in the HIL-214 Vaccine Trial, and (ii) the Company has announced the completion of subject enrollment for the HIL-214 Vaccine Trial, which shall involve the enrollment of approximately 3,000 or more subjects. All Term Loans are subject to a minimum draw amount of $5.0 million and no event of default under the Loan Agreement having occurred and is continuing. The borrowings under the Loan Agreement are collateralized by substantially all of the Company's assets, including intellectual property and certain other assets.

The Term Loans bear (a) cash interest at a floating rate of the higher of (i) the Wall Street Journal prime rate (or 5.00% if less) plus 1.05%, or (ii) 4.55%, and (b) additional interest at a per annum rate equal to 2.85%, with such interest being added to the outstanding principal balance of the Term Loans on a monthly basis. The monthly payments consist of interest-only through June 1, 2025 or, if prior to April 30, 2025, (x) the conditions to Term Loan 3 have been satisfied and (y) the Company has reasonably determined that (i) the HIL-214 Vaccine Trial has achieved the protocol-specified primary efficacy endpoint and (ii) HIL-214 has demonstrated acceptable safety results in the HIL-214 Vaccine Trial, and, as a result, the Company supports the initiation of a Phase 3 registrational trial as the next immediate step in the development of HIL-214, in each case subject to reasonable verification by Hercules, through June 1, 2026. Subsequent to the interest-only period, the Term Loans will be payable in equal monthly installments of principal, plus accrued and unpaid interest, through the maturity date of May 1, 2027. In addition, the Company is obligated to pay a final payment fee equal to the greater of (i) $2.1 million and (ii) 7.15% of the original principal amount of the Term Loans. The Company may elect to prepay all or a portion of the Term Loans prior to maturity, subject to a prepayment fee of up to 2.00% of the then outstanding principal balance and the pro rata application of such payment to the final payment fee. After repayment, no Term Loan amounts may be borrowed again.

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

2022 Incentive Award Plan

In April 2022, the Company's board of directors and stockholders approved the 2022 Incentive Award Plan (the "2022 Plan") under which the Company may grant stock options, restricted stock, dividend equivalents, restricted stock units, stock appreciation rights, and other stock or cash-based awards to its employees, consultants and directors. The 2022 Plan became effective in connection with the Company's IPO and will remain in effect until the tenth anniversary of its effective date, which will be April 28, 2032, unless earlier terminated by the Company's board of directors. The number of shares of the Company's common stock initially available for issuance under awards granted pursuant to the 2022 Plan was the sum of (1) 4,900,000 shares of the Company's common stock, plus (2) any shares remaining available for issuance under the 2021 Plan as of the effective date of the 2022 Plan, plus (3) any shares subject to outstanding awards under the 2021 Plan as of the effective date of the 2022 Plan that become available for issuance under the 2022 Plan thereafter in accordance with its terms. The number of shares initially available for issuance will be increased by an annual increase on January 1 of each calendar year beginning in 2023 and ending in and including 2032, equal to the lesser of (1) 5% of the shares of common stock outstanding on the final day of the immediately preceding calendar year and (2) such smaller number of shares as determined by the Company's board of directors. In connection with the Company's IPO, the Company's board of directors approved the grant under the 2022 Plan of stock options to purchase

an aggregate of 132,799 shares of its common stock to certain of the Company's employees, at an exercise price equal to the IPO price.

2022 Employee Stock Purchase Plan

In April 2022, the Company's board of directors and stockholders approved the 2022 Employee Stock Purchase Plan (the "2022 ESPP"). The 2022 ESPP became effective in connection with the Company's IPO. The 2022 ESPP permits eligible employees who elect to participate in an offering under the ESPP to have up to a specified percentage of their eligible earnings withheld, subject to certain limitations, to purchase shares of common stock pursuant to the 2022 ESPP. The price of common stock purchased under the 2022 ESPP is equal to 85% of the lower of the fair market value of the common stock on the first trading day of the offering period or the relevant purchase date. A total of 410,000 shares of the Company's common stock was initially reserved for issuance under the 2022 ESPP. In addition, the number of shares available for issuance under the 2022 ESPP will be annually increased on January 1 of each calendar year beginning in 2023 and ending in and including 2032, by an amount equal to the lesser of (1) 1% of the shares outstanding on the final day of the immediately preceding calendar year and (2) such smaller number of shares as is determined by the Company's board of directors, provided that no more than 10,000,000 shares of the Company's common stock may be issued under the 2022 ESPP.

Initial Public Offering

On May 3, 2022, the Company completed its IPO whereby it sold 13,529,750 shares of common stock at a public offering price of $17.00 per share, for net proceeds of approximately $210.3 million, after deducting underwriting discounts, commissions and offering costs of approximately $19.7 million. In addition, each of the following occurred in connection with the Company's IPO (i) the issuance of 10,672,138 shares of common stock upon the automatic conversion of August 2021 Notes, (ii) the expiration of the right granted to Takeda to receive an additional common stock warrant, (iii) the reclassification of the Takeda Warrant and August 2021 Notes to stockholders' equity at their fair values, and (iv) an increase in the number of authorized shares of the Company's common stock and preferred stock to 500,000,000 shares and 50,000,000 shares, respectively.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis and the unaudited interim financial statements included in this Quarterly Report on Form 10-Q should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2021 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in the Prospectus dated April 28, 2022 filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the Securities Act), with the Securities and Exchange Commission (SEC) on April 29, 2022 (the Prospectus).

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing, costs, design and conduct of our ongoing and planned preclinical studies and planned clinical trials for our product candidates, the timing and likelihood of regulatory filings and approvals for our product candidates, our ability to commercialize our product candidates, if approved, the impact of the COVID-19 pandemic on our business, plans and objectives of management for future operations and future results of anticipated product development efforts, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "continue" "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target" or "will" or the negative of these terms or other similar expressions. These forward-looking statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties and assumptions, including, without limitation, the risk factors described in Part II, Item 1A, "Risk Factors" of this Quarterly Report. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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, including safety and immunogenicity data from more than 800 pediatric subjects. A randomized, placebo-controlled Phase 2b field efficacy trial enrolled 4,712 adult subjects, and HIL-214 was well tolerated and demonstrated clinical proof of concept in preventing moderate-to-severe cases of AGE from norovirus infection. In September 2021, an open IND was transferred to us from Takeda, under which we initiated a Phase 2b clinical trial, NOR-212, in May 2022 to evaluate the safety, immunogenicity, and efficacy of HIL-214 in infants. In May 2022, we completed enrollment of the prespecified 200 subject run-in for NOR-212. We expect to resume enrollment in NOR-212 in the third quarter of 2022, following the prespecified safety assessment by the clinical trial's data monitoring committee. We expect to report interim immunogenicity results for the first 200 subjects of NOR-212 in the first half of 2023, and top-line safety and clinical efficacy results in the second half of 2023. 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 March 31, 2022, we had cash and cash equivalents of $111.3 million. From inception to March 31, 2022, we raised aggregate gross proceeds of $137.2 million from the issuance of convertible promissory notes. On May 3, 2022, we

completed our initial public offering (IPO), whereby we sold 13,529,750 shares of common stock at a public offering price of $17.00 per share, for net proceeds of approximately $210.3 million, after deducting underwriting discounts, commissions and offering costs of approximately $19.7 million.

We do not have any products approved for sale, have not generated any revenue and have incurred net losses since our inception. Our net losses for the three months ended March 31, 2022 and 2021 were $67.9 million and $1.5 million, respectively. As of March 31, 2022, we had an accumulated deficit of $173.1 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical development activities, other research and development activities and pre-commercialization activities. We expect our expenses and operating losses will increase substantially as we advance HIL-214 through clinical trials, seek regulatory approval for HIL-214, expand our clinical, regulatory, quality, manufacturing and commercialization capabilities, incur significant commercialization expenses for marketing, sales, manufacturing and distribution in anticipation of obtaining potential marketing approval for HIL-214, obtain, maintain, protect and enforce our intellectual property, expand our general and administrative support functions, including hiring additional personnel, and incur additional costs associated with operating as a public company.

Based on our current operating plan, we believe that our existing cash and cash equivalents, together with the net proceeds from our IPO, will be sufficient to meet our anticipated cash requirements through at least the next 12 months. We have never generated any revenue and do not expect to generate any revenue from product sales unless and until we successfully complete development of, and obtain regulatory approval for, HIL-214, which will not be for several years, if ever. Accordingly, until such time as we can generate significant revenue from sales of HIL-214, if ever, we expect to finance our cash needs through equity offerings, our existing Loan Agreement, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market vaccine candidates that we would otherwise prefer to develop and market ourselves.

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

License Agreement with Takeda

On July 2, 2021, we and Takeda Vaccines, Inc. (Takeda), a subsidiary of Takeda Pharmaceutical Company Limited, entered into a license agreement (the Takeda License), pursuant to which we exclusively in-licensed certain intellectual property rights to commercialize HIL-214 products worldwide (excluding Japan) (the Territory). We will be responsible, at

our cost, for the development, manufacture and commercialization of HIL-214 products. We are obligated to use commercially reasonable efforts to develop and commercialize HIL-214 products in the Territory, and to seek regulatory approval for such products throughout the world.

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

Transitional Services Agreement with Takeda

As contemplated by the Takeda License, on December 17, 2021, we and Takeda entered into a Transitional Services Agreement (the TSA). Pursuant to the TSA, Takeda has agreed to provide, on a transitional basis following the effective date of the Takeda License, certain services related to research and development and regulatory assistance services, oversight and management of ongoing clinical and research studies, and maintenance of certain third party vendor contracts. In consideration for the services provided under the TSA, we have agreed to pay certain specified amounts to Takeda in cash for such services and certain pass-through costs. For the three months ended March 31, 2022, we incurred $1.4 million of research and development expenses for Takeda's services.

Components of Results of Operations

Operating Expenses

Research and Development

During 2022 and 2021, 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.

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 for the three months ended March 31, 2022 relate to the Takeda License, and include an aggregate $2.5 million contingent payment upon the release of certain drug products and the completion of certain regulatory activities, which have no alternative future use.

General and Administrative

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

Interest Income

Interest income consists of interest on money market funds.

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 (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 condensed consolidated statements of operations.

In connection with our IPO, 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, 2020 and 2021 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 condensed consolidated statements of operations. All outstanding convertible promissory notes and related accrued interest converted into shares of our common stock upon the closing of our IPO.

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 Three Months Ended March 31, 2022 and 2021

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

	Three Months Ended March 31,		
	2022	2021	Change
Operating expenses:			
Research and development	$ 6,211	$ 267	$ 5,944
In-process research and development	2,500	—	2,500
General and administrative	2,603	1,198	1,405
Total operating expenses	11,314	1,465	9,849
Loss from operations	(11,314)	(1,465)	(9,849)
Other income (expense):			
Interest income	6	—	6
Interest expense	(2,064)	(9)	(2,055)
Change in fair value of convertible promissory notes	(17,073)	(73)	(17,000)
Change in fair value of warrant liabilities	(37,424)	—	(37,424)
Other income (expense)	(18)	1	(19)
Total other income (expense)	(56,573)	(81)	(56,492)
Net loss	$ (67,887)	$ (1,546)	$ (66,341)

Research and development expenses. Research and development expenses were $6.2 million and $0.3 million for the three months ended March 31, 2022 and 2021, respectively. The increase of $5.9 million primarily consisted of $3.0 million of clinical development expenses for HIL-214, $1.6 million of personnel-related expenses, $0.8 million of consulting expenses, $0.3 million of facility and related expenses and $0.2 million of stock-based compensation.

In-process research and development expenses. We had $2.5 million of in-process research and development expenses for the three months ended March 31, 2022 related to the payment in March 2022 of an aggregate $2.5 million contingent payment under the Takeda License upon the release of certain drug products and the completion of certain regulatory activities.

General and administrative expenses. General and administrative expenses were $2.6 million and $1.2 million for the three months ended March 31, 2022 and 2021, respectively. The increase of $1.4 million primarily consisted of $0.6 million of personnel-related expenses, $0.5 million in professional services expenses for accounting, audit, tax, valuation and other services, $0.1 million of stock-based compensation and $0.3 million of other expenses, offset by a decrease of $0.1 million in legal fees related to corporate and other matters.

Other income (expense). Other expense of $56.6 million for the three months ended March 31, 2022 primarily consisted of $2.1 million of interest expense on our outstanding convertible promissory notes, $17.1 million of other expense related to the increase in fair value of our convertible promissory notes and $37.4 million of other expense related to the increase

in fair value of the Takeda Warrant. Other expense of $0.1 million for the three months ended March 31, 2021 primarily consisted of $0.1 million of other expense related to the increase in the fair value of our convertible promissory notes.

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 primarily through the issuance of convertible promissory notes and the net proceeds raised from our IPO. As of March 31, 2022, we had cash and cash equivalents of $111.3 million. On May 3, 2022, we completed our IPO, whereby we sold 13,529,750 shares of common stock at a public offering price of $17.00 per share, for net proceeds of approximately $210.3 million, after deducting underwriting discounts, commissions and offering costs of approximately $19.7 million.

Term Loan Facility

On April 18, 2022, we entered into a Loan and Security Agreement (Loan Agreement) with Hercules Capital, Inc. (Hercules), as administrative and collateral agent, and the lenders party thereto, providing for term loans (Term Loans) of up to $75.0 million in the aggregate. We borrowed $5.0 million on April 18, 2022 and have the right to borrow up to an additional $10.0 million through December 15, 2022 and up to an additional $15.0 million through June 30, 2023 (collectively, Term Loan 1). We also have the right to borrow up to $20.0 million through June 30, 2023 (Term Loan 2). In addition, we have the right to borrow up to $25.0 million through March 31, 2024 (Term Loan 3), provided that on or prior to March 31, 2023, (i) we have announced that our planned Phase 2b clinical trial evaluating the safety, immunogenicity, and efficacy of HIL-214 in infants (HIL-214 Vaccine Trial) will continue without material adverse modification after completion of our planned interim safety and immunogenicity analysis on the first 200 evaluable subjects in the HIL-214 Vaccine Trial and (ii) we have announced the completion of subject enrollment for the HIL-214 Vaccine Trial, which shall involve the enrollment of approximately 3,000 or more subjects. All Term Loans are subject to a minimum draw amount of $5.0 million and no event of default having occurred and be continuing. The borrowings under the Loan Agreement are collateralized by substantially all of our assets, including intellectual property and certain other assets.

The Term Loans bear (a) cash interest at a floating rate of the higher of (i) the Wall Street Journal prime rate (or 5.00% if less) plus 1.05%, or (ii) 4.55%, and (b) additional interest at a per annum rate equal to 2.85%, with such interest being added to the outstanding principal balance of the Term Loans on a monthly basis. The monthly payments consist of interest-only through June 1, 2025 or, if prior to April 30, 2025, (x) the conditions to Term Loan 3 have been satisfied and (y) we have reasonably determined that (i) the HIL-214 Vaccine Trial has achieved the protocol-specified primary efficacy endpoint and (ii) HIL-214 has demonstrated acceptable safety results in the HIL-214 Vaccine Trial, and, as a result, we support the initiation of a Phase 3 registrational trial as the next immediate step in the development of HIL-214, in each case subject to reasonable verification by Hercules, through June 1, 2026. Subsequent to the interest-only period, the Term Loans will be payable in equal monthly installments of principal, plus accrued and unpaid interest, through the maturity date of May 1, 2027. In addition, we are obligated to pay a final payment fee equal to the greater of (i) $2.1 million and (ii) 7.15% of the original principal amount of the Term Loans. We may elect to prepay all or a portion of the Term Loans prior to maturity, subject to a prepayment fee of up to 2.00% of the then outstanding principal balance and the pro rata application of such payment to the final payment fee. After repayment, no Term Loan amounts may be borrowed again.

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

Convertible Promissory Note Financings

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

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

Funding Requirements

Based on our current operating plan, we believe that our existing cash and cash equivalents, together with the net proceeds from our IPO, will be sufficient to meet our anticipated cash requirements through at least the next 12 months. In particular, we expect the net proceeds from our IPO will allow us to complete enrollment and dosing in our Phase 2b NOR-212 study, technical transfer and manufacturing readiness for producing clinical trial supply for a Phase 3 study, and will be used for working capital and other general corporate purposes, which may include the hiring of additional personnel, capital expenditures and the costs of operating as a public company. 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, the Loan Agreement, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or

restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, intellectual property, future revenue streams, research programs or vaccine candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our vaccine candidates even if we would otherwise prefer to develop and market such vaccine candidates ourselves.

Cash Flows

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

	Three Months Ended March 31,	
	2022	2021
Net cash provided by (used in):		
Operating activities	$ (10,715)	$ (417)
Investing activities	(2,500)	—
Financing activities	(99)	—
Net decrease in cash and cash equivalents	$ (13,314)	$ (417)

Operating Activities

Net cash used in operating activities was $10.7 million and $0.4 million for the three months ended March 31, 2022 and 2021, respectively. Net cash used in operating activities for the three months ended March 31, 2022 was primarily due to our net loss of $67.9 million and a net change of $0.1 million in our operating assets and liabilities, offset by $57.3 million of noncash charges primarily related to the $37.4 million change in fair value of the Takeda Warrants, $17.1 million change in fair value of the August 2021 Notes, $2.5 million related to acquired in-process research and development and $0.3 million of stock-based compensation. Net cash used in operating activities for the three months ended March 31, 2021 was due to our net loss of $1.5 million, offset by a $1.1 million net change in operating assets and liabilities.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2022 was primarily due to the $2.5 million contingent payment we paid under the Takeda License. We had no investing activities for the three months ended March 31, 2021.

Financing Activities

Net cash used in financing activities for the three months ended March 31, 2022 was primarily due to our payment of $0.1 million of costs related to our IPO. We had no financing activities for the three months ended March 31, 2021.

Contractual Obligations and Commitments

As of March 31, 2022, there have been no material changes outside the ordinary course of our business to the contractual obligations we reported in “Management’s discussion and analysis of financial condition and results of operations – Contractual obligations and commitments,” included in the Prospectus.

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 condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States (GAAP). The preparation of our condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements and accompanying notes. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for

making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

As of March 31, 2022, there have been no material changes to our critical accounting policies and estimates from those disclosed in "Management's discussion and analysis of financial condition and results of operations – Critical accounting policies and estimates," included in the Prospectus.

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 condensed consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of our IPO, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 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 Item 1 of Part I, "Notes to Condensed Consolidated Financial Statements — Note 1 — Organization, Basis of Presentation and Summary of Significant Accounting Policies" of this Quarterly Report.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable to a smaller reporting company.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information

is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

Due to a transition period established by SEC rules applicable to newly public companies, our management is not required to evaluate the effectiveness of our internal control over financial reporting until after the filing of our Annual Report on Form 10-K for the year ended December 31, 2022. As a result, this Quarterly Report on Form 10-Q does not address whether there have been any changes in our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

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

Summary of Risks Related to Our Business

The risk factors included below are a summary of the principal risk factors associated with an investment in us. The summary below does not contain all of the risks we face. You should carefully consider this summary, together with the more detailed discussion of these risks and uncertainties set forth below in this Item 1A.

- We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.
- We currently depend entirely on the success of HIL-214, which is our only vaccine candidate. If we are unable to advance HIL-214 in clinical development, obtain regulatory approval and ultimately commercialize HIL-214, or experience significant delays in doing so, our business will be materially harmed.
- Clinical and preclinical development involves a lengthy and expensive process with an uncertain outcome, and the results of prior clinical trials and studies of HIL-214 are not necessarily predictive of our future results. We have not completed any clinical trials for HIL-214 and we may not have favorable results in our clinical trials, or receive regulatory approval on a timely basis, if at all.
- Any difficulties or delays in the commencement or completion, or the termination or suspension, of our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- Use of HIL-214 or any 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.

- We rely heavily on the Takeda License to provide us intellectual property rights to develop and commercialize HIL-214. If the Takeda License is terminated, we would lose our rights to develop and commercialize HIL-214.
- We rely on third parties to conduct many of our clinical trials and preclinical studies and to manufacture HIL-214, and these third parties may not perform satisfactorily which could delay, prevent or impair our development efforts or ability to seek or obtain regulatory approval for HIL-214.
- We face significant competition, and if our competitors develop technologies or vaccine candidates more rapidly than we do or their technologies are more effective, our business and our ability to develop and successfully commercialize products may be adversely affected.
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.
- 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.
- The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

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

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

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2019, and we have no products approved for clinical commercial sale. To date, we have focused primarily on organizing and staffing our company, business planning, raising capital, in-licensing intellectual property related to our initial vaccine candidate, HIL-214, and preparing for our 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 $67.9 million and $1.5 million for the three months ended March 31, 2022 and 2021, respectively. 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 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, 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 March 31, 2022, we had cash and cash equivalents of $111.3 million. Based on our current operating plan, we believe that our existing cash and cash equivalents, together with the net proceeds from our IPO, will enable us to fund our operations for at least the next 12 months. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect and need to seek additional funds sooner than planned. Our existing cash and cash equivalents will not be sufficient to complete development of HIL-214, or any future vaccine candidate, and 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 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.

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, restrict our operations or require us to relinquish rights to our technologies or vaccine candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, our loan and security agreement with Hercules Capital, Inc., as administrative and collateral agent, and the lenders party thereto, debt financings, or other capital sources, including potential collaborations, license agreements and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. The Loan Agreement includes, and any future

debt financing and preferred equity financing, if available, may involve agreements that include, covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

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

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

We currently depend entirely on the success of HIL-214, which is our 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.

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. For example, we may not be able to meet expected timeframes for the enrollment of our ongoing Phase 2b clinical trial of HIL-214 or the reporting of data from such trial. Despite promising preclinical or clinical results, any vaccine candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for vaccine candidates in our industry is high, particularly in the early stages of development.

The results from preclinical studies or clinical trials of a vaccine candidate or a competitor's vaccine candidate in the same class may not predict the results of later clinical trials of such vaccine candidate, and interim, topline, or preliminary results of a clinical trial are not necessarily indicative of final results. Vaccine candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. In particular, while HIL-214 has been studied by Takeda in an extensive clinical program that included nine clinical trials, we do not know how HIL-214 will perform in our 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.

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 initiated 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, data readouts and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA, EMA or comparable foreign regulatory authorities disagreeing as to the implementation of our clinical trials;
- any failure or delay in reaching an agreement with contract research organizations (CROs) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- obtaining approval from one or more institutional review boards (IRBs) or ethics committees at clinical trial sites;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- major changes or amendments to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with good clinical practice (GCP) requirements or applicable regulatory guidelines in other countries;
- manufacturing sufficient quantities of HIL-214 and placebo for use in clinical trials, which could be materially impacted by the COVID-19 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, heath 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.

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, including war, relevant to such foreign countries.

In addition, many of the factors that cause, or lead to, the termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a vaccine candidate. We may make formulation or manufacturing changes to HIL-214 or any 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 initiated a Phase 2b clinical trial of HIL-214 in infants in May 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 ongoing 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 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 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.

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 ongoing 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, 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, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. 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, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, including by temporarily halting certain activities from December 29, 2021 to February 7, 2022. 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.

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 parties fails to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting preclinical studies, clinical trials or other development activities that could harm our competitive position.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we work to carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

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

We do not own or operate manufacturing facilities and have no plans to develop our own clinical or commercial-scale manufacturing capabilities. Pursuant to the Takeda License, we entered into a clinical manufacturing and supply agreement with Takeda for the supply of HIL-214 for our Phase 2b clinical trial in infants. 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, placebo 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 and placebo 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 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 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;
- 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. 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;

- 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-related illness, 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 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, 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;
- 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 March 31, 2022, we had 31 full-time employees, including 20 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.

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

As of the inception of the Loan Agreement on April 18, 2022, we borrowed $5.0 million and have the right to borrow an additional $70.0 million in the aggregate (collectively, Term Loans) subject to the achievement of certain specified financing and clinical development milestones (as described in the section titled “Management’s discussion and analysis

of financial condition and results of operations—Liquidity and capital resources—Term Loan Facility") and no event of default having occurred and be continuing. All obligations under the Term Loans are secured by a first priority lien on substantially all of our assets, including intellectual property and certain other assets. As a result, if we default on any of our obligations under the Loan Agreement, the lenders could foreclose on their security interest and liquidate some or all of the collateral, which would harm our business, financial condition and results of operations and could require us to reduce or cease operations.

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

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any

materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS), information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives), teaching hospitals and other healthcare providers, as well as ownership and investment interests held by such healthcare professionals and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biotechnology companies to report information on the pricing of certain drug products; and some state and local laws that require the registration or pharmaceutical sales representatives.

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

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers 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 March 31, 2022 and a 1% reduction from April 1, 2022 through June 30, 2022, unless additional Congressional action is taken. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for products. At the federal level, the 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-related and other personal information in certain circumstances. These laws are evolving rapidly and may differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. By way of example, the California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020, gives California residents individual privacy rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability and many similar laws have been proposed at the federal level and in other states. Further, the California Privacy Rights Act (CPRA) 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. The new standard contractual clauses apply only to the transfer of personal data outside of the EEA and not the United Kingdom; the United Kingdom's Information Commissioner's Office launched a public consultation on its draft revised data transfers mechanisms in August 2021 and the United Kingdom standard contractual clauses came into force in March 2022, with a two-year grace period. 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.

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. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Any security breach or other incident, whether actual or perceived, were to occur, it 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. We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or result in the unauthorized disclosure of or access to personally identifiable information or individually identifiable health information, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. 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.

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.

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.

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 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

Prior to our IPO, there was no public market for our common stock. An active, liquid and orderly market for our common stock may not develop or be sustained.

Prior to our IPO, there was no public market for our common stock. Our common stock only recently began trading on the Nasdaq Global Select Market ("Nasdaq"), and we can provide no assurance that we will be able to develop an active trading market for our common stock. Even if an active market is developed, it may not be sustained. If an active market for our common stock is not sustained, it may be difficult for you to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

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

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

- recalls or adverse developments or publicity;
- results of our preclinical studies and clinical studies, and the results of trials of our competitors or those of other companies in our market sector;

- our ability to enroll subjects in our future clinical trials;
- regulatory approval of HIL-214 or any 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, including inflation and increases and decreases in interest rates, many of which are beyond our control;
- announcement of geopolitical events (including in relation to the conflict between Russia and Ukraine);
- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- changes in accounting standards, policies, guidelines, interpretations or principles.

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

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

As of May 31, 2022, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 65.1% of our outstanding common stock. As a result, such persons, acting together, have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

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

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

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

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

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

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

In connection with our IPO, our directors and officers and holders of substantially all of our outstanding securities prior to our IPO 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 the Prospectus for the IPO, 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 Securities 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.

After the lock-up agreements expire, these shares of common stock will be eligible for sale in the public market, except that shares held by our directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act.

In addition, the holders of 15,547,035 shares of our outstanding common stock, or approximately 49.1% of our total outstanding common stock based on shares outstanding as of May 31, 2022, and Takeda with respect to the registration of 5,883,500 shares of our common stock underlying the Takeda Warrant, are 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. Further, Takeda is entitled to the same rights with respect to the registration of 5,883,500 shares of our common stock underlying the Takeda Warrant. 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 our IPO . However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer", as defined under the Exchange Act, our annual gross revenue exceeds $1.07 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 cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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

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

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

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;

- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

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

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

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

General risk factors

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

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting 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.

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

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, blizzards and other extreme weather conditions, fires, public health pandemics or epidemics (including, for example, the COVID-19 pandemic) and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers to produce HIL-214. Our ability to obtain clinical supplies of HIL-214 or any 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. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. 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 our IPO or other ownership changes.

We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income (subject to limitations), if any, until such unused losses expire (if at all). As of December 31, 2021, we had net operating loss (NOL) carryforwards of $13.4 million for federal income tax purposes and $2.9 million for state income tax purposes. Our state NOL carryforwards begin to expire in various amounts in 2041. Our federal NOL carryforwards will not expire but may generally only be used to offset 80% of taxable income, which may require us to pay federal income taxes in future years despite generating federal NOL carryforwards in prior years.

In addition, our NOL carryforwards and other tax attributes are subject to review and possible adjustment by the Internal Revenue Service (IRS) and state tax authorities. Furthermore, in general, under Section 382 of the U.S. Internal Revenue

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

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

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance. In particular, the U.S. government may enact significant changes to the taxation of business entities including, among others, an increase in the corporate income tax rate and the imposition of minimum taxes or surtaxes on certain types of income. The likelihood of these changes being enacted or implemented is unclear. We are currently unable to predict whether such changes will occur. If such changes are enacted or implemented, we are currently unable to predict the ultimate impact on our business. We urge our investors to consult with their legal and tax advisors with respect to any changes in tax law and the potential tax consequences of investing in our common stock.

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

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

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

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

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Unregistered Sales of Equity Securities

During the quarter ended March 31, 2022, we granted to certain of our employees and consultants options to purchase an aggregate of 479,085 shares of common stock at an exercise price of $8.05 per share. The stock options 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 Rule 506 promulgated thereunder as a transaction not involving any public offering.

Use of Proceeds

On April 28, 2022, our registration statement on Form S-1 (File No. 333-264159) was declared effective by the SEC for our IPO. At the closing of the offering on May 3, 2022, we sold 13,529,750 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,764,750 additional shares, at an initial public offering price of $17.00 per share and received gross proceeds of $230.0 million, which resulted in net proceeds to us of approximately $210.3 million, after deducting underwriting discounts and commissions of approximately $16.1 million and offering-related transaction costs of approximately $3.6 million. None of the expenses associated with the initial public offering were paid to directors, officers, persons owning ten percent or more of any class of equity securities, or to their associates, or to our affiliates. J.P. Morgan Securities LLC, SVB Securities LLC, Stifel, Nicolaus & Company, Incorporated and Guggenheim Securities, LLC acted as joint book-running managers for the offering.

There has been no material change in the planned use of proceeds from our IPO from that described in the Prospectus.

Issuer Repurchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation of HilleVax, Inc.	8-K	5/3/22	3.1	
3.2	Amended and Restated Bylaws of HilleVax, Inc.	8-K	5/3/22	3.2	
4.1	Specimen stock certificate evidencing the shares of common stock	S-1	4/6/22	4.1	
4.2	Warrant to purchase shares of common stock issued to Takeda Vaccines, Inc., dated July 2, 2021	S-1	4/6/22	4.2	
4.3	Note Purchase Agreement, dated August 31, 2021, by and among the Registrant and the other parties party thereto	S-1	4/6/22	4.3	
10.1#	HilleVax, Inc. 2022 Incentive Award Plan and form of stock option agreement and form of restricted stock unit agreement thereunder	S-1/A	4/25/22	10.2	
10.2#	HilleVax, Inc. 2022 Employee Stock Purchase Plan	S-1/A	4/25/22	10.3	
10.3#	Non-Employee Director Compensation Program	S-1/A	4/25/22	10.4	
10.4#	Form of Indemnification Agreement for Directors and Officers	S-1	4/6/22	10.9	
10.5	Loan and Security Agreement, dated April 18, 2022, by and among the Registrant and Hercules Capital, Inc.	S-1/A	4/18/22	10.12	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				X

# Indicates management contract or compensatory plan.

* This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

HilleVax, Inc.

Date: June 8, 2022

By: /s/ Robert Hershberg, M.D., Ph.D.

Robert Hershberg, M.D., Ph.D.
Chairman, President and Chief Executive Officer (Principal Executive Officer)

Date: June 8, 2022

By: /s/ David Socks

David Socks
Chief Financial Officer and Chief Business Officer (Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert Hershberg, M.D., Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of HilleVax, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 8, 2022

By: /s/ Robert Hershberg, M.D., Ph.D.

Robert Hershberg, M.D., Ph.D.
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David Socks, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of HilleVax, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 8, 2022

By: /s/ David Socks

David Socks
Chief Financial Officer and Chief Business Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of HilleVax, Inc. (the "Company") for the quarter ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert Hershberg, M.D., Ph.D., as Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: June 8, 2022

By: /s/ Robert Hershberg, M.D., Ph.D.
Robert Hershberg, M.D., Ph.D.
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of HilleVax, Inc. (the "Company") for the quarter ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Socks, as Chief Financial Officer and Chief Business Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: June 8, 2022

By: /s/ David Socks
David Socks
Chief Financial Officer and Chief Business Officer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.