

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

FORM 8-K

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

Date of Report (Date of earliest event reported): January 6, 2023

HilleVax, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-41365
(Commission
File Number)

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

75 State Street, Suite 100 - #9995
Boston, Massachusetts
(Address of principal executive offices)

02109
(Zip Code)

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

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (Sec.230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Sec.240.12b-2 of this chapter).

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.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Appointment of Chief Financial Officer

Effective January 6, 2023, the Board of Directors (the “Board”) of HilleVax, Inc. (the “Company”) appointed Shane Maltbie, the Company’s Vice of President, Finance, to serve as the Company’s Chief Financial Officer. Additionally, effective as of such date, Mr. Maltbie was designated as the Company’s principal financial officer and principal accounting officer. On January 6, 2023, in connection with Mr. Maltbie’s promotion, David Socks notified the Company of his resignation as Chief Financial Officer, including his resignation as the Company’s principal financial officer and principal accounting officer. Mr. Socks will continue his employment with the Company as its Chief Business Officer.

Mr. Maltbie, age 41, has served as the Company’s Vice President of Finance since December 2021. Prior to joining the Company, Mr. Maltbie was the Vice President of Finance at TScan Therapeutics, Inc. and prior to that the Vice President of Finance at Axcella Health Inc. Mr. Maltbie started his career in the Boston office of Deloitte & Touche LLP in the audit practice. Mr. Maltbie is a certified public accountant in the Commonwealth of Massachusetts (inactive license). He received his B.S. in Accounting and Business Management from Hartwick College and his MSA from Northeastern University.

There are no family relationships between either Mr. Maltbie and any director or executive officer of the Company, and each of them has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(k) of Regulation S-K.

In connection with Mr. Maltbie’s appointment as the Company’s Chief Financial Officer, the Company entered into an amended and restated employment letter with Mr. Maltbie. The employment letter for Mr. Maltbie provides for an annual base salary of \$430,000, and an annual bonus with a target amount equal to 40% of Mr. Maltbie’s annual base salary. Additionally, under the employment letter, Mr. Maltbie is eligible to participate in all employee benefit plans and programs generally available to similarly situated employees of our company and is entitled to vacation benefits in accordance with our policies.

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

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

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

In addition, to the extent that any payment or benefit received in connection with a change in control would be subject to an excise tax under Section 4999 of the Internal Revenue Code, such payments and/or benefits will be subject to a "best pay cap" reduction if such reduction would result in a greater net after-tax benefit to Mr. Maltbie than receiving the full amount of such payments.

Amended and Restated Employment Letter with Robert Hershberg

Effective January 6, 2023, the Company and our Chief Executive Officer, Robert Hershberg, entered into an amended and restated employment letter. The terms and conditions of Dr. Hershberg's employment letter are the same as in the original employment letter, as amended and restated, except as noted below.

Under his amended employment letter, Dr. Hershberg is entitled to receive an annual base salary of \$635,000, increased from \$600,000;

Upon a termination without "cause" or resignation for "good reason" (each, as defined in the employment letter) outside of a change in control period (as defined below), Mr. Hershberg will be entitled to all of the same severance benefits in the original employment letter, except that he will be entitled to: (1) continuation of his base salary for 12 months (such applicable period, the "severance period"), which was increased from 9 months, (2) payments of the COBRA premiums for his and his eligible dependents until the earliest of (a) the end of the new 12-month severance period (increased from 9 months), (b) expiration of his eligibility for continuation coverage under COBRA, or (c) the date he becomes eligible for health insurance coverage in connection with his new employment, and (3) acceleration of the vesting of all outstanding equity awards that would have vested during the severance period (provided that Dr. Hershberg's founders' shares will be governed by the terms of his stock restriction agreement);

Upon a termination without cause or resignation for good reason that occurs during the change in control period, Dr. Hershberg will be entitled to all of the same severance benefits in the original employment letter, except (1) the severance period is 18 months (increased from 12 months), (2) Dr. Hershberg will be entitled to a lump sum payment equal to his target bonus for the year during which such termination occurs (rather than a pro-rated portion of his target bonus as provided in the original employment letter), and (3) payments of the COBRA premiums for his and his eligible dependents until the earliest of (a) the end of the new 18-month severance period (increased from 12 months), (b) expiration of his eligibility for continuation coverage under COBRA, or (c) the date he becomes eligible for health insurance coverage in connection with his new employment; and

To the extent that any payment or benefit received in connection with a change in control would be subject to an excise tax under Section 4999 of the Internal Revenue Code, such payments and/or benefits will be subject to a "best pay cap" reduction if such reduction would result in a greater net after-tax benefit to Dr. Hershberg than receiving the full amount of such payments.

Amended and Restated Employment Letter with David Socks

Effective January 6, 2023, the Company and our Chief Business Officer, David Socks, entered into an amended and restated employment letter. The terms and conditions of Mr. Sock's employment letter are the same as in the original employment letter, as amended and restated, except as noted below.

Under his amended employment letter, Mr. Socks' position with the Company will be Chief Business Officer, and he is entitled to receive an annualized base salary of \$477,000, increased from \$450,000;

Upon a termination without cause or resignation for good reason that occurs within the change in control period, Mr. Socks will be entitled to all of the same severance benefits in the original employment letter, except he will be entitled to a lump sum payment equal to his target bonus for the year during which such termination occurs (rather than a pro-rated portion of his target bonus as provided in the original employment letter); and

To the extent that any payment or benefit received in connection with a change in control would be subject to an excise tax under Section 4999 of the Internal Revenue Code, such payments and/or benefits will be subject to a "best pay cap" reduction if such reduction would result in a greater net after-tax benefit to Mr. Socks than receiving the full amount of such payments.

Amended and Restated Employment Letter with Aditya Kohli

Effective January 6, 2023, the Company and our Chief Operating Officer, Aditya Kohli, entered into an amended and restated employment letter. The terms and conditions of Dr. Kohli's employment letter are the same as in the original employment letter, as amended and restated, except as noted below.

Under his amended employment letter, Dr. Kohli is entitled to receive an annual base salary of \$500,000, increased from \$490,000;

Upon a termination without cause or resignation for good reason that occurs during the change in control period, Dr. Kohli will be entitled to all of the same severance benefits in the original employment letter, except he will be entitled to a lump sum payment equal to his target bonus for the year during which such termination occurs (rather than a pro-rated portion of his target bonus as provided in the original employment letter); and

To the extent that any payment or benefit received in connection with a change in control would be subject to an excise tax under Section 4999 of the Internal Revenue Code, such payments and/or benefits will be subject to a "best pay cap" reduction if such reduction would result in a greater net after-tax benefit to Dr. Kohli than receiving the full amount of such payments.

The foregoing description of the terms of the amended and restated employment letters for Drs. Hershberg and Kohli and Messrs. Maltbie and Socks is a summary which does not purport to be complete and is subject to and qualified in its entirety by reference to each executive's amended and restated employment letter, copies of which will be filed as exhibits to the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

Item 7.01 Regulation FD Disclosure.

On January 9, 2023 representatives of the Company will be attending meetings with investors and analysts and making a presentation in connection with the J.P. Morgan Healthcare Conference. During these meetings and the presentation, the Company will reference the corporate slide presentation attached as Exhibit 99.1 to this Current Report on Form 8-K, which is incorporated herein by reference.

The Company's updated corporate presentation has been posted to the Company's website, www.hillevax.com. The Company plans to use its website to disseminate future updates to its corporate presentation and does not intend to file or furnish a Form 8-K alerting investors each time the presentation is updated.

The information set forth in this Item 7.01 is being furnished pursuant to Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, whether made before or after the date hereof, except as expressly provided by specific reference in such a filing.

By filing this Current Report on Form 8-K and furnishing the information in this Item 7.01, the Company makes no admission as to the materiality of Item 7.01 in this report or the presentation available on the Company's website. The information contained in the presentation is summary information that is intended to be considered in the context of the Company's filings with the Securities and Exchange Commission (the "SEC") and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time as its management believes is appropriate or as required by applicable law. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases, by updating the Company's website or through other public disclosure.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit</u>	<u>Description</u>
99.1	Slide Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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 hereunto duly authorized.

HilleVax, Inc.

Date: January 8, 2023

By: /s/ Paul S. Bavier

Name: Paul S. Bavier

Title: General Counsel and Chief Administrative Officer



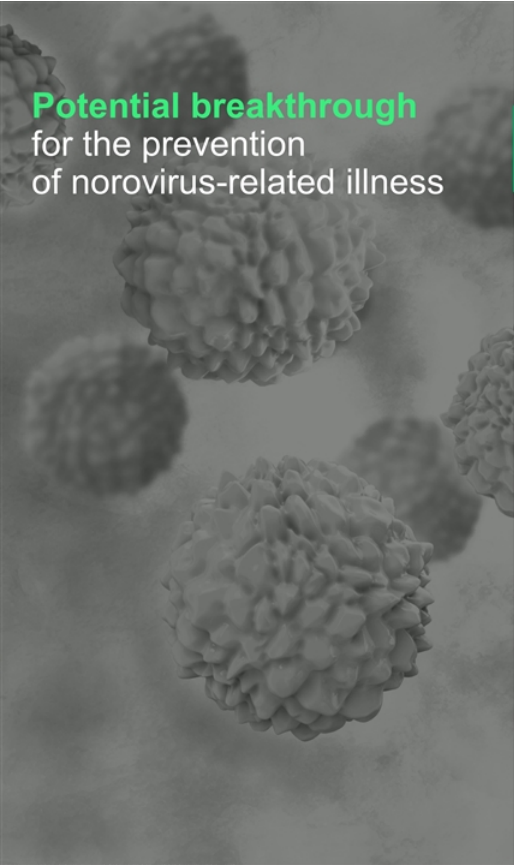
CORPORATE PRESENTATION

JANUARY 2023

Disclaimer

We caution you that this presentation contains forward-looking statements of HilleVax, Inc. (“HilleVax,” “we,” “us” or similar terms). All statements other than statements of historical facts contained in this presentation, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing, costs, design and conduct of our planned and potential clinical trials and preclinical studies for HIL-214 and any future vaccine candidates, the timing and likelihood of regulatory filings and approvals for HIL-214 and any future vaccine candidates, our ability to commercialize our vaccine candidates, if approved, the impact of COVID-19 on our business, the pricing and reimbursement of our vaccine candidates, if approved, the potential to develop future vaccine candidates, the potential benefits of strategic collaborations and our intent to enter into any strategic arrangements, the timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated product development efforts, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. The inclusion of forward-looking statements should not be regarded as a representation by us that any of our plans will be achieved. Actual results may differ from those set forth in this presentation due to the risks and uncertainties inherent in our business, including, without limitation: we currently depend entirely on the success of HIL-214, our only vaccine candidate, and we have not yet completed any clinical trials of HIL-214; potential delays in the commencement, enrollment, and completion of clinical trials and preclinical studies; our dependence on third parties in connection with manufacturing, research and clinical and preclinical testing; unexpected adverse side effects or inadequate immunogenicity or efficacy of HIL-214 or any future vaccine candidates that may limit their development, regulatory approval, and/or commercialization; unfavorable results from clinical trials; results from prior clinical trials and studies not necessarily being predictive of future results; our ability to maintain uninterrupted business operations due to the COVID-19 pandemic, including delaying or disrupting our clinical trials, manufacturing and supply chain; regulatory developments in the United States and foreign countries; our reliance on intellectual property rights under our license agreement with Takeda Vaccines, Inc.; our ability to obtain, maintain and enforce intellectual property protection for our vaccine candidates; we may use our capital resources sooner than we expect; and other risks described in our filings with the SEC, including under the heading “Risk Factors” in the prospectus we filed with the SEC on April 29, 2022 and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this presentation, and except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.



Potential breakthrough
for the prevention
of norovirus-related illness

HIL-214

Significant unmet medical need

Potential to be first vaccine approved for norovirus-related illness

9 Phase I & II studies completed in >4,500 subjects

Clinical PoC demonstrated in adult Phase IIb study

Phase IIb clinical trial ongoing in 3,000 infants

Multi-billion dollar commercial potential

Senior Leadership



Rob Hershberg, MD, PhD
CEO & Chair

EVP BD & CSO, Celgene
CEO, VentiRx
CMO, Dendreon



Astrid Borkowski, MD, PhD
CMO

VP, Head of Clinical Development, Takeda Vaccines
CMO, Europe, Novartis Vaccines



Paul Bavier, JD
GC & CAO

GC, Velos Bio
GC, Avedro
GC, Bidel



Aditya Kohli, PhD
COO

CBO, Phathom Pharma
VP BD, Scout Bio
Engagement Manager, McKinsey



Anju Chatterji, PhD
CTO

SVP, Biologics Dev & Mfg, Catalyst Bio
VP, Biologics Mfg, Exelixis



David Socks
CBO

CEO & CFO, Phathom Pharma
COO, Incline Therapeutics
SVP, Cadence Pharmaceuticals



Shane Maltbie, CPA
CFO

VP Finance, TScan Therapeutics
VP Finance, Axcella



Ozzie Berger
SVP Regulatory

VP, Head of Regulatory, Vaccines, GSK
VP, RA Head, Global Vaccines R&D, GSK



Lynn Ferrucci
VP HR

EVP HR, Ziopharm Oncology
SVP HR, Clinical Data

Board of Directors



Shelley Chu, MD, PhD
Partner, Lightspeed



Gary Dubin, MD
President, Global Vaccine Business Unit, Takeda



Julie Gerberding, MD, MPH
President, Merck Vaccines
Director, CDC



Patrick Heron
Managing General Partner, Frazier



Rob Hershberg, MD, PhD, Chair
Co-founder & CEO, HilleVax
EVP BD & CSO, Celgene



Jeri Hilleman
Audit chair/CFO of multiple public life sciences companies



Aditya Kohli, PhD
Co-founder & COO, HilleVax



Jaime Sepulveda, MD, PhD, MPH
Exec Dir, UCSF Institute for Global Health Sciences
Director, NIH Mexico



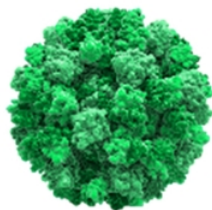
Susan Silbermann
President, Pfizer Vaccines
President, Pfizer Emerging Markets

Norovirus is the most common cause of acute gastroenteritis in US and worldwide¹

Highly contagious virus causing diarrhea, vomiting, stomach pain, fever, and headache

Complications from dehydration can be severe, including death

Easily transmitted via person-to-person contact, contaminated foods or surfaces



Key vulnerable populations

Young children

Endemic, incidence of norovirus highest among young children²

Adults

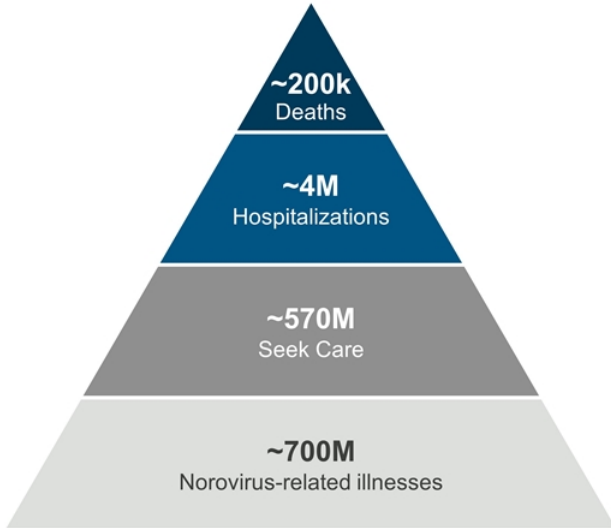
Outbreaks among HCPs, military, food handlers, travelers, other groups

Older adults

Outbreaks in nursing homes and hospitals, higher likelihood of hospitalization / death

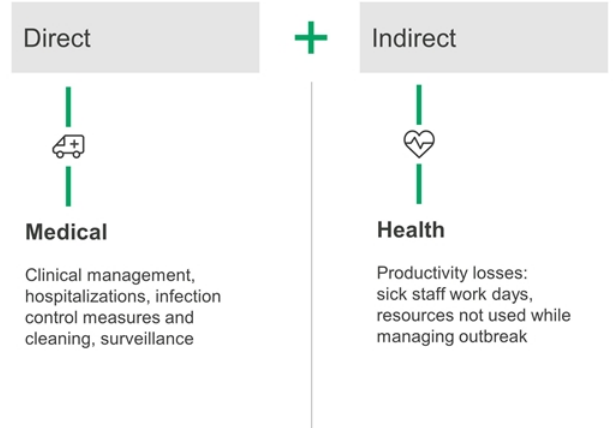
1. Centers for Disease Control and Prevention website, 2021
2. Saito et al., 2014; Cannon et al., 2019

Norovirus global annual burden is high...



... resulting in direct and indirect costs of ~\$10b in US and ~\$60b globally^{1,2}

Costs

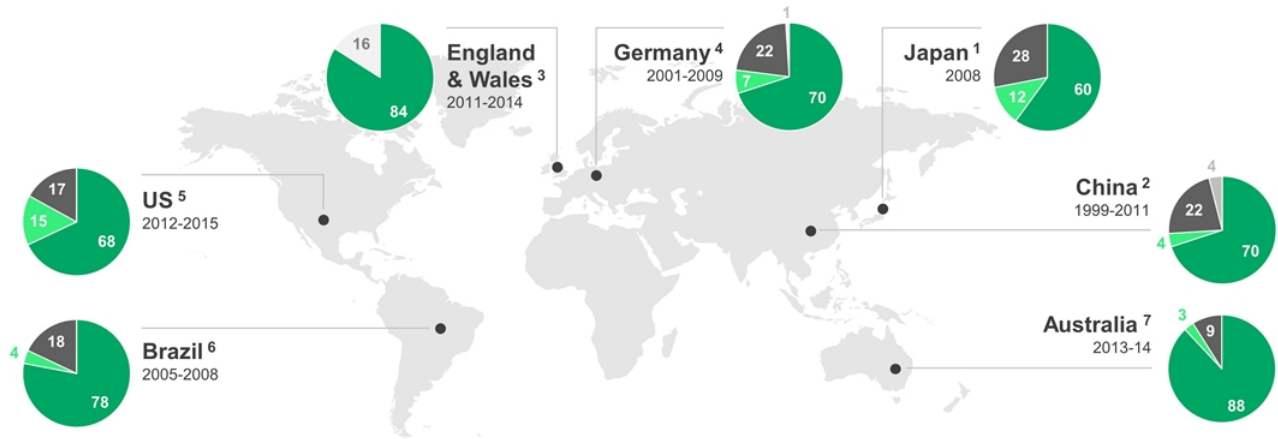


1. Bartsch et al., 2016 2. Bartsch et al., 2020

GI and GI.4 genotypes comprise the majority of norovirus infections worldwide

Norovirus incidence by strain % total incidence

■ GI.4 ■ GI ■ Other GI ■ Mix ■ Other



1. Inaida S et al., PLoS One 2013
 2. Yu Y Biomed Res Int. 2014; 2014 (ID 196169): 1-13
 3. Public Health England. PHE National norovirus and rotavirus report. 10 Jul 2014
 4. Bernard H, et al. Epi infect 2014; 142(1): 63-74

5. Shah et al. CDC MMWR 2017
 6. Ferreira MS, et al. J Med Virol 2010
 7. Lim KL, et al. PLoS One 2016

HIL-214 comprises VLPs for major genotypes GI.1 and GI.4

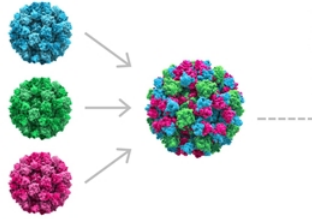
GI.1 selected based on its potential to promote a broad immune response to GI strains

GI.4 selected because it is estimated to be responsible for nearly two-thirds of norovirus illness¹

1. Kumthip et al., 2019

1 Virus-Like Particles (VLPs)

Conformationally correct representation of the virus capsid

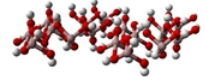


Consensus Strategy

Presents epitopes from three different norovirus GI.4 strains on one VLP

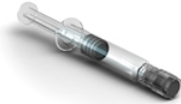
2 Adjuvant

Designed to enhance immunogenicity and stability of VLPs in solution



Aluminum hydroxide

3 Norovirus Vaccine



Prefilled Syringe (intramuscular)

Large clinical program demonstrates immunogenicity, efficacy, and safety/tolerability

Trial No.	Phase	Design	Study Population	HIL-214 safety, n	HIL-214 immuno, n
LV01-103	I/II	R, DB, Pbo, NoV challenge for safety, immunogenicity, and efficacy	18 - 50 years	N/A ¹	N/A ¹
LV03-104	I	R, DB, Pbo, dose/age-escalation for safety and immunogenicity	18 - 85 years	66	66
LV03-105	I/II	R, DB, Pbo, NoV challenge for safety, immunogenicity, and efficacy	18 - 50 years	67	67
NOR-210	II	Study to generate serum controls for validation of serology assay	18 - 49 years	50	50
NOR-107	II	R, DB, for safety, immunogenicity, dose finding, and adjuvant justification	18 - 64 years	418	418
NOR-201	II	RD, DB for safety and immunogenicity	18 - 49 years	425	425
NOR-204	II	R, DB for safety, immunogenicity, dose finding and formulation selection	18 - >85 years	311	311
NOR-211	IIb	R, DB, Pbo for efficacy, safety, and immunogenicity	18 - 49 years; military recruits	2,355	97
NOR-202	II	R, DB for safety, immunogenicity, dose finding and adjuvant justification	6wks - 9 years	839	839
TOTAL				4,531	2,273

1. Intranasal formulation of vaccine, not included in HIL-214 safety and immunogenicity subject numbers
R: randomized. DB: double-blind. OL: open label. Pbo: placebo-controlled

**We believe that
HIL-214 clinical data
have substantially
de-risked the program**

HIL-214 Key Clinical Accomplishments

- ✓ Dose selection
- ✓ Adjuvant selection
- ✓ Immunogenicity in infants/children
- ✓ Immunogenicity in adults/older adults
- ✓ Efficacy proof-of-concept in adults
- ✓ Safety/tolerability profile
- ✓ 5-year safety and immunogenicity

SAFETY

>4,500 subjects (839 pediatric subjects) received vaccine in clinical studies

In adults, local AEs all mild/moderate with systemic AEs similar to placebo

Infant AEs largely mild to moderate with short duration (<3-4 days)

NOR-202, NOR-211, NOR-204 studies, WHO, FDA prescribing information

These data are presented for informational purposes only, as the comparisons in the tables to the right are not based on head-to-head clinical studies and may not be comparable due to differences in vaccine design, disease under evaluation, trial designs and populations studied.

HIL-214 clinical AE profile comparable to commercial vaccines

Pediatric safety

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

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

Adult safety

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

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

HIL-214 IMMUNOGENICITY

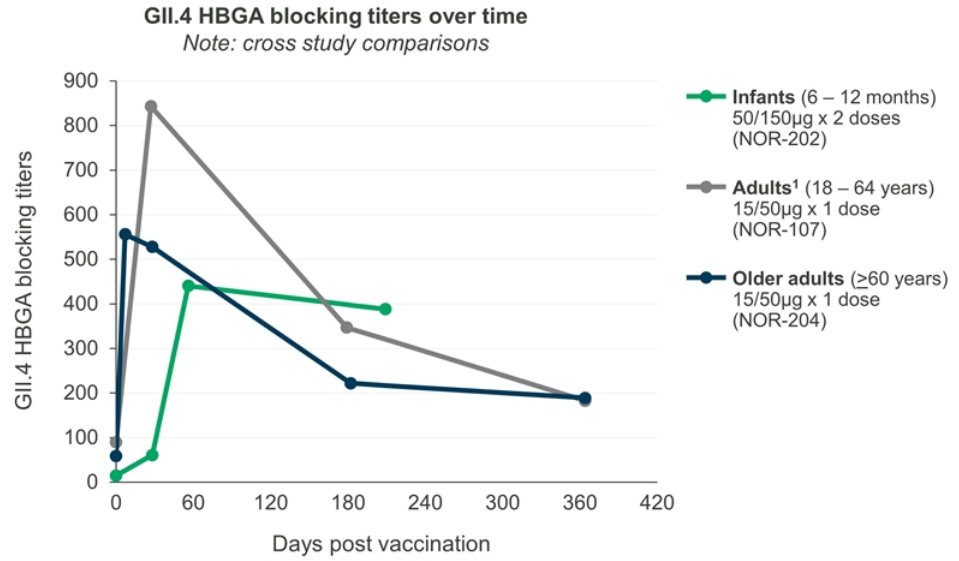
HBGA is an attachment factor on the surface of intestinal epithelia known to promote norovirus entry into host cells

Measurement of HBGA-blocking antibodies is the primary method to assess vaccine immunogenicity against norovirus

Data from long-term immunogenicity study in adults (NOR-213) has shown titers to date **above baseline at year 5**

NOR-202, NOR-107, and NOR-204 studies

HBGA blocking response following vaccination with HIL-214



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

CLINICAL POC
demonstrated in
US Navy recruits

4,712 subjects

2 season, single site study had very few cases of HIL-214 vaccine strains of norovirus

Clinical PoC demonstrated across any observed norovirus strains due to heterotypic protection provided by HIL-214

Sherwood et al, Vaccine 2020

Phase 2b demonstrated **reduction in moderate-to-severe AGE**

	Pathogen	Cases of moderate-to-severe AGE		Viral efficacy	
		Placebo n = 2,357	HIL-214 n = 2,355	%	p value
1°	HIL-214 vaccine strain only ¹	5 (0.2)	1 (<0.1)	80.0	p = 0.142
2°	Any NoV strain	26 (1.1)	10 (0.4)	61.8	p = 0.0097
Post-hoc	GII.2 strain	21	9	57.4	p = 0.0321

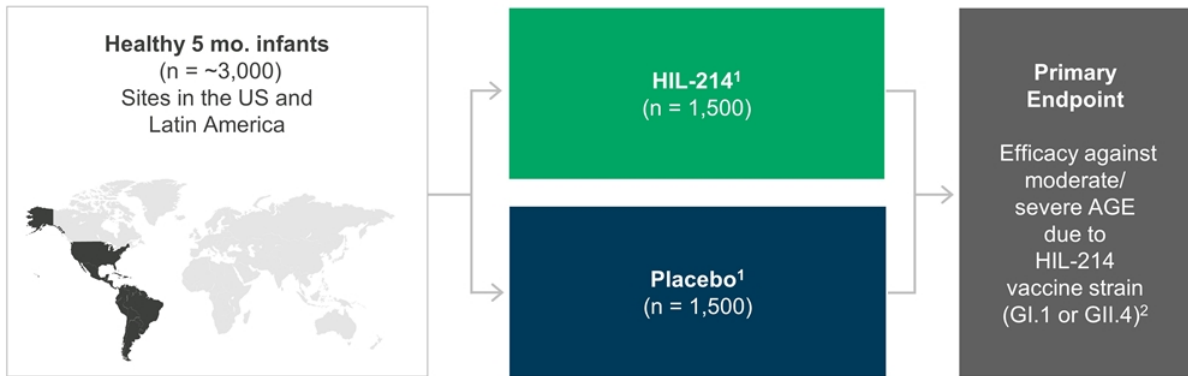
1. GI.1 or GII.4

We intend to focus our initial development primarily on the **infant population**

Advantages of studying HIL-214 in infants

- ✓ Endemic pattern of infection
- ✓ Higher prevalence of GII.4
- ✓ Comparison to subjects without pre-existing immunity
- ✓ Regulatory and operational precedent of rotavirus vaccines

NEST-IN1 Phase 2b pediatric study ongoing



¹ Vaccinations at Day 1 and Day 29 - 57

² Key secondary endpoints may include evaluation of efficacy against any GI or GII norovirus strain

NEST-IN1 has achieved significant milestones since 2Q22 initiation

NEST-IN1 updates

DMC completed Cohort 1 (203 subjects) safety review and **recommended study continuation** without modification

Cohort 1 **immune responses¹ were consistent** with prior infant studies of HIL-214

Enrollment continues for remaining subjects

Topline data expected **1Q24**

1. Pan-Ig antibody responses 28 days post second dose

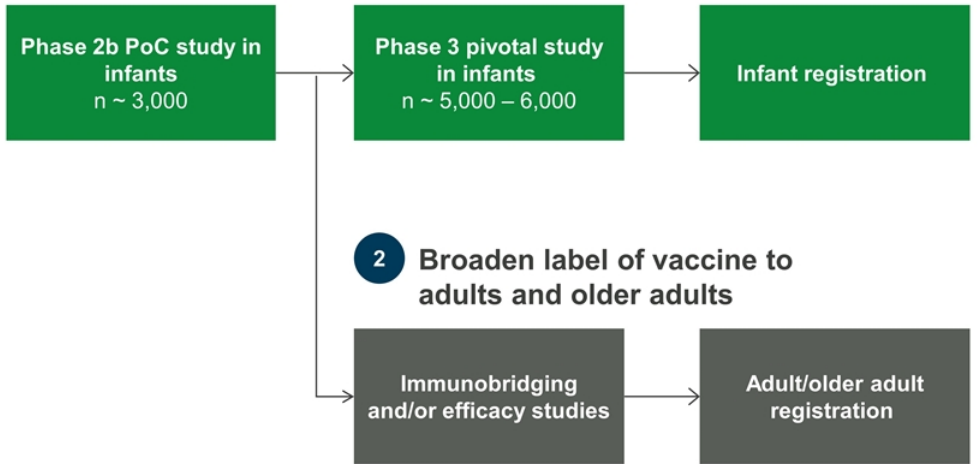
Development and regulatory strategy

Initial clinical program focused on infant population

Followed by immunobridging and/or efficacy studies in older adults

Clinical program and concurrent epidemiology and pharmacoeconomic studies to support potential ACIP recommendations

1 Establish initial indication in infants



ACIP recommendation will be sought for both the infant and older adult populations

Norovirus burden of disease compares favorably to other viruses which have vaccines that carry ACIP recommendations

Norovirus burden (today) is comparable to rotavirus and shingles burden (pre-vaccines) in the United States

Disease	Age	US cases	US hospitalizations	US deaths	US economic burden (in 2020 dollars)
Norovirus	≤ 4 years	2.8 million	12,000	20	\$1.2 billion
	5 – 64 years	15.7 million	34,000	70	\$6.4 billion
	≥ 65 years	3.7 million	50,000	1,250	\$3.2 billion
	All ages	22 million	96,000	1,350	\$10.6 billion
Rotavirus (pre-vaccine)	≤ 5 years	2.7 million	70,000	60	\$1.5 billion
Shingles (pre-vaccine)	≥ 50 years	1.0 million	46,000	80	\$2.4 billion

Potential multi-billion dollar commercial opportunity

1 INFANTS/TODDLERS

ROTAVIRUS VACCINES AS A CASE STUDY

Similar burden of disease between norovirus and rotavirus

Two rotavirus vaccines were launched in 2006 and 2008 (RotaTeq and Rotarix)

ACIP recommendation for routine infant use

\$1.5B global net sales in 2021

\$210-360 per rotavirus vaccine course (US)



2 OLDER ADULTS

SHINGLES VACCINES AS A CASE STUDY

CDC recommended vaccine for older adults

Zostavax approved in 2006; rapidly replaced by Shingrix approved Oct 2017

ACIP recommendation for adults over 50

\$2.3B global net sales of Shingrix in 2021

\$200-300 per shingles vaccine course (US)

+ OTHER ADULTS including HCPs, military, travelers, food handlers

STRONG CAPITAL POSITION

As of September 30, 2022:

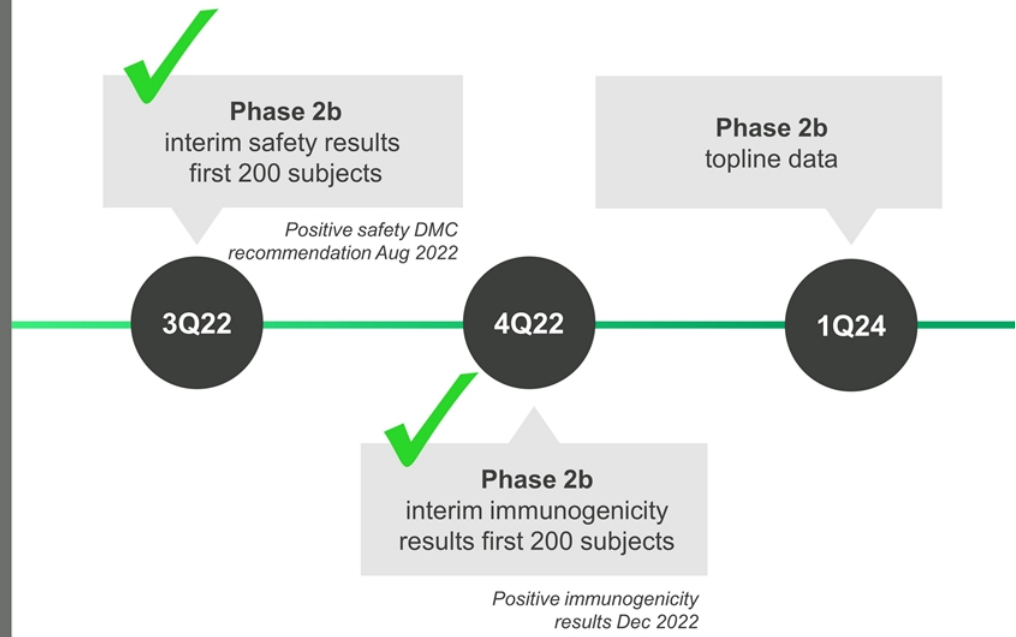
\$292.1M cash

\$75M term loan:

\$5M drawn + up to \$70M available prior to P2b topline results¹

¹ Subject to certain milestones and conditions

Anticipated milestones





NASDAQ: HLVX*

- ✓ **Most advanced** norovirus vaccine candidate
- ✓ **Clinical PoC** demonstrated in adults
- ✓ **Phase IIb study ongoing** in 3,000 infants
- ✓ **Blockbuster** potential commercial opportunity
- ✓ **Highly experienced** leadership team