### 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 8, 2024

# 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.)

321 Harrison Avenue Boston, Massachusetts (Address of principal executive offices)

021118

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

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

	owing provisions:  Written communications pursuant to Rule 425 under the	no Securities Act (17 CEP 220 425)	
	1	, ,	
	Soliciting material pursuant to Rule 14a-12 under the E	,	
	Pre-commencement communications pursuant to Rule	14d-2(b) under the Exchange Act (17 CF)	R 240.14d-2(b))
	Pre-commencement communications pursuant to Rule	13e-4(c) under the Exchange Act (17 CFI	R 240.13e-4(c))
Secu	urities 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	HIVY	The Nasdag 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.  $\Box$ 

### Item 7.01 Regulation FD Disclosure.

On January 8, 2024 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.

ExhibitDescription99.1Slide 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, 2024

By: // Seal S. Bavier
Name: Paul S. Bavier
Title: General Counsel and Chief Administrative Officer



# CORPORATE PRESENTATION JANUARY 2024

### 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 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, 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; unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may adversely affect our business and financial condition and the broader economy and biotechnology industry; regulatory developments in the United States and foreign countries; any future impacts to our business resulting from the conflict between Russia and Ukraine or other geopolitical developments outside our control; 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 prior press releases and our filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our annual report on Form 10-K 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 hereof, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. 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.



# HilleVax January 2024





unmet need



Multi-billion dollar commercial opportunity



**Clinical PoC** demonstrated in adults and near-term large Phase IIb infant readout in mid-2024

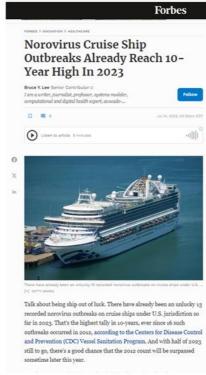


Strong capital position with \$324.4M in cash at **September 30, 2023** 



### Norovirus in the news...



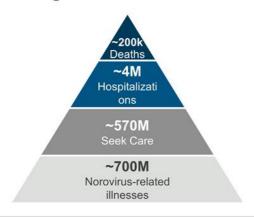


"And these symptoms can be quite severe too. Norovirus often isn't just your typical I'm-feeling-a-little-sick-so-I-may-pass-on-shuffleboard type of gastroenteritis. No, a norovirus infection can consist of projectile vomiting and explosive diarrhea. Projecting your voice, feelings, or insecurities is one thing. Projecting your vomit is something completely different."

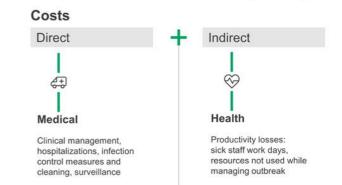
Bruce Y. Lee, Forbes 2023



# Norovirus global annual burden is high...



# ... resulting in direct and indirect costs of ~\$10b in US and ~\$60b globally1,2



### Key vulnerable populations

### Young children

Endemic, incidence of norovirus highest among young children<sup>2</sup>

### Adults

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

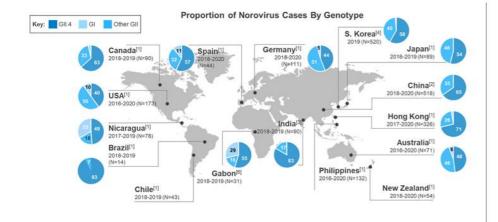
### Older adults

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

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



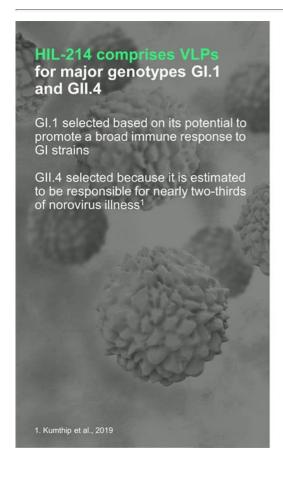
## GII.4 remains the dominant genotype associated with the majority of norovirus infections worldwide

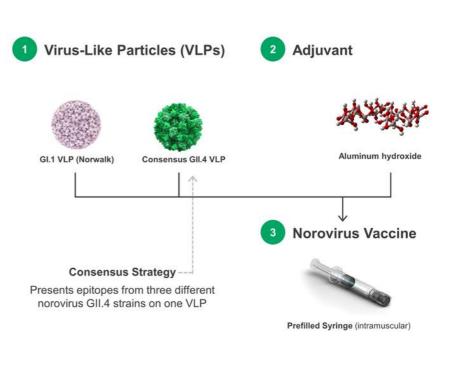


- GII.4 infections in 2021-2022 represented approximately 60% of infections in children <57
- GII.4 infections resulted in 75% of hospitalizations and 82% of deaths based on a meta analysis of 843 norovirus outbreaks8



<sup>&</sup>lt;sup>1</sup> Cannon et al. Emerg Infect Dis. 2021.; <sup>2</sup> Fang et al. BMC Infect Dis. 2021.; <sup>3</sup> Lo et al. Arch Virol. 2021.; <sup>4</sup> Cho et al. J Med Virol. 2021.; <sup>5</sup> Rossouw et al. Viruses. 2021.; <sup>6</sup> Manouana et al. Viruses. 2021. <sup>7</sup> NoroSurv: A global network for norovirus strain surveillance – data retrieved on 17 Apr 2023; <sup>6</sup> Adapted from Desai et al. CID 2012.



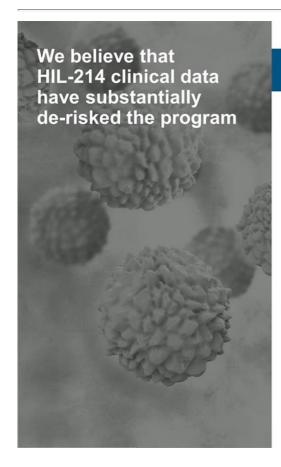


# Large clinical program demonstrates immunogenicity, efficacy, and safety/tolerability

Trial No.	Phase	Design	Study Population	HIL-214 safety, n=	HIL-214 immuno, n=
LV01-103	1/11	R, DB, Pbo, NoV challenge for safety, immunogenicity, and efficacy	18 - 50 years	N/A <sup>1</sup>	N/A <sup>1</sup>
LV03-104	1	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
NEST-IN1 <sup>2</sup>	Ilb	R, DB, Pbo for efficacy, safety, and immunogenicity	5 months	1,500	1,500
NOR-109 <sup>2</sup>	1	R, DB, Pbo, safety and immunogenicity	5 months	14	14
NOR-206 <sup>2</sup>	II	R, DB, Pbo, safety and immunogenicity when HIL-214 is concomitantly administered with routine infant vaccines	4 months	77	77
NOR-215 <sup>2</sup>	II	SA, OL, safety and immunogenicity	18 – 49 years	185	185
TOTAL <sup>2</sup>				6,307	4,049



Intranasal formulation of vaccine, not included in HIL-214 safety and immunogenicity subject numbers
 NEST-IN1, NOR-109, NOR-206, and NOR-215 clinical trials ongoing, final subject numbers still estimated for study completion
 R: randomized. DB: double-blind. OL: open label. Pbo: placebo-controlled



# 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 across age groups
- √ 5-year safety and immunogenicity in adults



### **SAFETY**

>6,000 subjects (2,430 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	220 220	6 weeks – 6 months <sup>s</sup>	9 - 21%1	2 - 9%1	19 - 28%1	
NOFOVITUS	HIL-214	6 months - 9 years <sup>5</sup>	21 - 33% <sup>1</sup>	7 - 8%1	10 - 20%1	
Pneumococcal	Prevnar 13	2 – 15 months	20 - 42%3,4	24 - 37% <sup>3</sup>	80 - 86%3	
Rotavirus	Rotarix	6 – 24 weeks	Oral – N/A	25 - 28%1	42 - 52%1	
Rotavirus	RotaTeq	5 – 36 weeks	Oral – N/A	17 - 20%2	4 - 7%²	
Pertussis	Daptacel (TDaP)	2 - 6 months	1 - 6%2.4	8 - 24%2	32 - 40%²	
Pertussis	Whole cell DTP	2 – 6 months	5 - 11962.4	65 - 74% <sup>2</sup>	73 - 85%²	
MMRV	M-M-R II & Varivax	12 - 23 months	10 - 16%4	15%	7%	
MMKV	ProQuad	12 - 23 months	8-14%4	22%	7%	
Polio	OPV	2 months - 6 years	Oral - N/A	< 1%	< 196	

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

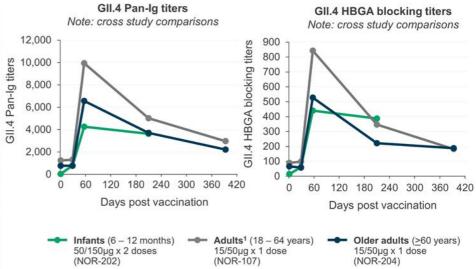
Disease	Vaccine	Age	Local reactions	Systemic reactions	
			Pain at injection site	Fever > 38°C	Headache
	214	18 to 49 years4	48%	6%	35%
Norovirus	HIL-214	>60 years5	33%	<1%	8%
501/10 10	Comirnaty	16 to 55 years	78 - 84%1	4 - 16%	44 - 54%1
COVID-19	Moderna	18 to 64 years	87 - 90%1	1 - 17%	35 - 63%1
HPV	Gardasil 9	16 to 26 years	71 - 74%²	2 - 3%²	15%
	Afluria	18 to 64 years	48%	1%	22%
Influenza	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

# Functional and binding 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 Clinical PoC demonstrated across any observed norovirus strains due to heterotypic protection provided by HIL-214 Sherwood et al, Vaccine 2020

# Phase 2b in adults demonstrated reduction in moderate-to-severe acute gastroenteritis

	Cases of m	Vira	Viral efficacy		
	Pathogen	<b>Placebo</b> n = 2,357	<b>HIL-214</b> n = 2,355	%	p value
1°	HIL-214 vaccine strain only <sup>1</sup>	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. Gl.1 or Gll.4

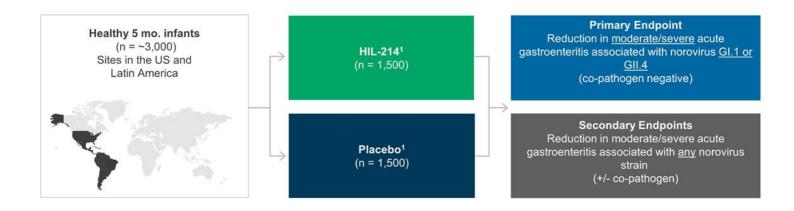




# Advantages of studying HIL-214 in infants

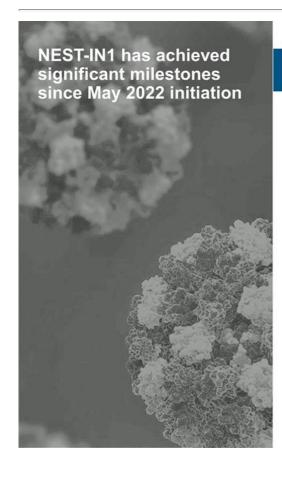
- Endemic pattern of infection
- ✓ Higher prevalence of GII.4
- Comparison to subjects without pre-existing immunity
- Regulatory and operational precedent of rotavirus vaccines

# **NEST-IN1 Phase 2b pediatric study ongoing**



1 Vaccinations at Day 1 and Day 29 - 57

OHILLEVAX 14



# **NEST-IN1** updates

Data Monitoring Committee completed recommended study continuation after safety review in August 2022

First 200 subjects immune responses<sup>1</sup> were consistent with prior infant studies of HIL-214 in November 2022

Enrollment completed with over 3,000 infants in April 2023

Topline data expected mid-2024 – Clinical safety and clinical efficacy on all subjects

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



# Other ongoing supporting studies of HIL-214

Study #	Phase	Design	Subjects	Status	Purpose
NOR-109	1	R, DB, Pbo, safety and immunogenicity	5 months of age	Enrollment complete	Enable inclusion of Japanese infants in planned Phase III clinical trial of HIL-214
NOR-206	II	R, DB, Pbo, safety and immunogenicity when HIL-214 is concomitantly administered with routine infant vaccines	4 months of age	Enrollment complete	Generate data on concomitant administration with routine pediatric vaccines
NOR-215	II	SA, OL, safety and immunogenicity	18 – 49 years	Enrollment complete	Generate serum for immunological assays and reference material

R: randomized. SA: single arm. DB: double-blind. OL: open label. Pbo: placebo-controlled



# **Development and** regulatory strategy

Initial clinical program focused on infant population

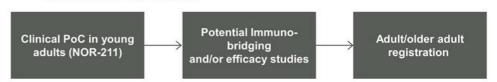
Followed by immuno-bridging and/or efficacy studies in older adults

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

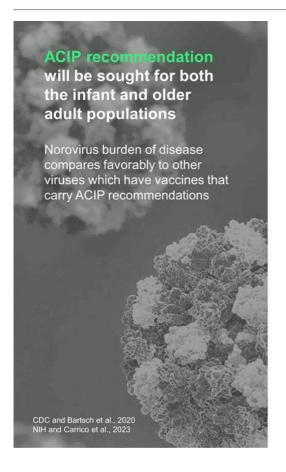
Establish initial indication in infants



Broaden label of vaccine to adults and older adults



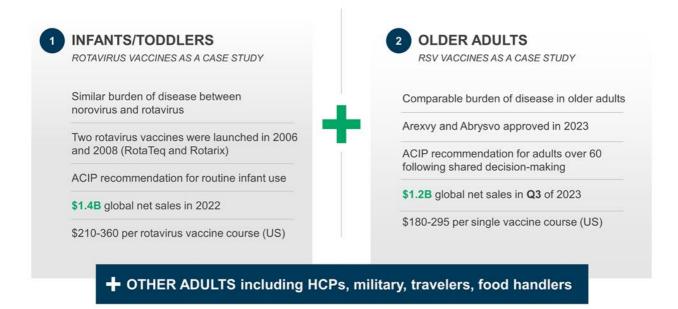




### Norovirus burden (today) is comparable to rotavirus, shingles, and RSV burden (pre-vaccines) in the United States

Disease	Age	US cases	US hospitalizations	US deaths	US economic burden (in 2020 dollars)
	≤ 4 years	2.8 million	12,000	20	\$1.2 billion
	5 – 64 years	15.7 million	34,000	70	\$6.4 billion
Norovirus	≥ 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
RSV (pre-vaccine)	≥ 60 years	2.5 million	100,000	8,000	\$7.4 billion

# Potential multi-billion dollar commercial opportunity



# HilleVax announces exclusive license with Kangh



# HilleVax and Kangh Announce Exclusive License Agreement for Hexavalent VLP Norovirus Vaccine Candidate Outside of China

Collaboration leverages HilleVax's leading norovirus vaccine development expertise and adds a Phase 1-ready next-generation program to HilleVax's pipeline

BOSTON and CHENGDU, China, Jan. 08, 2024 (GLOBE NEWSWIRE) -HilleVax, Inc. (Nasdaq: HLVX), a clinical-stage biopharmaceutical
company focused on developing and commercializing novel vaccines,
and Chengdu Kanghua Biological Products Co., Ltd. (Kangh) (SHE:
300841), a biopharmaceutical company engaged in the research,
development, production, and sale of bioproducts, today announced
the entry into an exclusive license agreement for rights to Kangh's
hexavalent virus-like particle (VLP) vaccine candidate for norovirus,
referred to by HilleVax as HIL-216, outside of Greater China.

HIL-216 includes VLPs for six of the most common norovirus genotypes, including GI.1, GII.2, GII.3, GII.4, GII.6, and GII.17. The Investigational New Drug (IND) application for HIL-216 was cleared by the U.S. FDA in September 2023. As part of the exclusive license agreement, Kangh will supply HIL-216 for use in HilleVax's near-term clinical trials, including a Phase 1 trial that HilleVax expects to initiate in 2024.

# Building towards a longterm norovirus vaccine leadership position

HIL-216 includes VLPs for six of the most common norovirus genotypes, including Gl.1, Gll.2, Gll.3, Gll.4, Gll.6, and Gll.17

Kangh to supply HIL-216 for use in near-term clinical trials

# Addition of HIL-216 to portfolio through collaboration with Kangh





Follow-on hexavalent norovirus vaccine candidate

Selected genotypes cover approximately 90% of norovirus infections worldwide

IND cleared, Phase 1 ready vaccine candidate

Leverages HilleVax's VLP development capabilities



# **STRONG CAPITAL POSITION**

As of September 30, 2023:

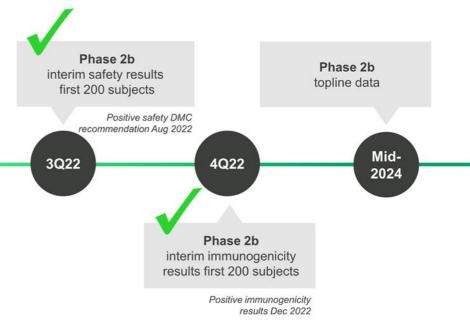
\$324.4M cash, cash equivalents & marketable securities1

\$75M term loan<sup>2</sup>:

\$25M drawn

<sup>1</sup> Includes proceeds of September 2023 financing <sup>2</sup> Full draw subject to certain milestones and conditions

# **Anticipated milestones**





# NASDAQ: HLVX



- Most advanced norovirus vaccine candidate
- Clinical PoC demonstrated in adults
- Phase IIb study readout in mid-2024 on 3,000 infants
- Next gen hexavalent VLP vaccine candidate licensed
- Large potential commercial opportunity

23