

**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 September 30, 2024

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

(State or other jurisdiction of
incorporation or organization)

321 Harrison Avenue, Boston, Massachusetts

(Address of principal executive offices)

85-0545060

(I.R.S. Employer
Identification No.)

02118

(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 November 4, 2024, the registrant had 49,806,070 shares of common stock, \$0.0001 par value per share, outstanding.

Table of Contents

	<u>Page</u>	
PART I	<u>FINANCIAL INFORMATION</u>	1
Item 1.	<u>Financial Statements (Unaudited)</u>	1
	<u>Condensed Consolidated Balance Sheets</u>	1
	<u>Condensed Consolidated Statements of Operations and Comprehensive Loss</u>	2
	<u>Condensed Consolidated Statements of Stockholders' Equity</u>	3
	<u>Condensed Consolidated Statements of Cash Flows</u>	5
	<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	31
Item 4.	<u>Controls and Procedures</u>	31
PART II	<u>OTHER INFORMATION</u>	31
Item 1.	<u>Legal Proceedings</u>	31
Item 1A.	<u>Risk Factors</u>	31
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	32
Item 3.	<u>Defaults Upon Senior Securities</u>	32
Item 4.	<u>Mine Safety Disclosures</u>	32
Item 5.	<u>Other Information</u>	32
Item 6.	<u>Exhibits</u>	33
	<u>Signatures</u>	34

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	<u>September 30,</u> <u>2024</u>	<u>December 31,</u> <u>2023</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 103,764	\$ 216,678
Marketable securities	85,546	86,805
Prepaid expenses and other current assets	7,860	7,195
Total current assets	197,170	310,678
Property and equipment, net	9,775	14,018
Operating lease right-of-use assets	12,022	18,082
Restricted cash	1,631	1,631
Other assets	24	25
Total assets	\$ 220,622	\$ 344,434
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,208	\$ 7,461
Accrued expenses (includes related party amounts of \$72 and \$33, respectively)	9,082	18,553
Accrued interest	—	134
Current portion of operating lease liability	3,546	3,118
Total current liabilities	13,836	29,266
Operating lease liability, net of current portion	21,427	22,831
Long-term debt, net of debt discount	—	25,244
Other long-term liabilities	1,086	1,568
Total liabilities	36,349	78,909
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; authorized shares— 50,000,000 at September 30, 2024 and December 31, 2023; no shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, \$0.0001 par value; authorized shares— 500,000,000 at September 30, 2024 and December 31, 2023; issued shares—49,795,054 and 48,497,853 at September 30, 2024 and December 31, 2023, respectively; outstanding shares—49,468,133 and 47,666,438 at September 30, 2024 and December 31, 2023, respectively	5	5
Additional paid-in capital	686,968	654,986
Accumulated other comprehensive loss	(821)	(907)
Accumulated deficit	(501,879)	(388,559)
Total stockholders' equity	184,273	265,525
Total liabilities and stockholders' equity	\$ 220,622	\$ 344,434

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development (includes related party amounts of \$36, \$55, \$93, and \$252, respectively)	\$ 20,165	\$ 27,308	\$ 72,744	\$ 73,425
In-process research and development	—	—	15,325	—
General and administrative	6,215	6,603	22,836	19,629
Impairment charges	—	—	8,235	—
Total operating expenses	26,380	33,911	119,140	93,054
Loss from operations	(26,380)	(33,911)	(119,140)	(93,054)
Other income (expense):				
Interest income	1,353	1,690	5,453	6,717
Interest expense	(1,853)	(717)	(3,318)	(1,666)
Other income	1,057	1,123	3,685	1,397
Total other income	557	2,096	5,820	6,448
Net loss	\$ (25,823)	\$ (31,815)	\$ (113,320)	\$ (86,606)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	166	(28)	55	(65)
Pension and other postemployment benefits	(50)	7	31	3
Total comprehensive loss	\$ (25,707)	\$ (31,836)	\$ (113,234)	\$ (86,668)
Net loss per share, basic and diluted	\$ (0.52)	\$ (0.81)	\$ (2.31)	\$ (2.26)
Weighted-average shares of common stock outstanding, basic and diluted	49,382,277	39,039,553	49,008,614	38,252,981

See accompanying notes.

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensiv e Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at June 30, 2024	49,289,852	\$ 5	\$ 681,918	\$ (937)	\$ (476,056)	\$ 204,930
Vesting of restricted shares	178,281	—	—	—	—	—
Stock-based compensation	—	—	5,050	—	—	5,050
Unrealized gain on marketable securities	—	—	—	166	—	166
Pension and other postemployment benefits	—	—	—	(50)	—	(50)
Net loss	—	—	—	—	(25,823)	(25,823)
Balance at September 30, 2024	<u>49,468,133</u>	<u>\$ 5</u>	<u>\$ 686,968</u>	<u>\$ (821)</u>	<u>\$ (501,879)</u>	<u>\$ 184,273</u>
Balance at June 30, 2023	38,049,186	\$ 4	\$ 538,865	\$ (322)	\$ (319,784)	\$ 218,763
Vesting of restricted shares	168,164	—	—	—	—	—
Stock-based compensation	—	—	3,946	—	—	3,946
Issuance of common stock under share-based compensation arrangements	1,000	—	7	—	—	7
Issuance of common stock in connection with underwritten public offering, net	9,200,000	1	107,749	—	—	107,750
Unrealized loss on marketable securities	—	—	—	(28)	—	(28)
Pension and other postemployment benefits	—	—	—	7	—	7
Net loss	—	—	—	—	(31,815)	(31,815)
Balance at September 30, 2023	<u>47,418,350</u>	<u>\$ 5</u>	<u>\$ 650,567</u>	<u>\$ (343)</u>	<u>\$ (351,599)</u>	<u>\$ 298,630</u>

See accompanying notes.

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

	<u>Common Stock</u>		Additional Paid-in Capital	Accumulated Other Comprehensiv e Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at December 31, 2023	47,666,438	\$ 5	\$ 654,986	\$ (907)	\$ (388,559)	\$ 265,525
Vesting of restricted shares	695,885	—	—	—	—	—
Stock-based compensation	—	—	16,305	—	—	16,305
Issuance of common stock under share-based compensation arrangements	88,860	—	790	—	—	790
Issuance of common stock in connection with at-the-market offering, net	1,016,950	—	14,887	—	—	14,887
Unrealized gain on marketable securities	—	—	—	55	—	55
Pension and other postemployment benefits	—	—	—	31	—	31
Net loss	—	—	—	—	(113,320)	(113,320)
Balance at September 30, 2024	<u>49,468,133</u>	<u>\$ 5</u>	<u>\$ 686,968</u>	<u>\$ (821)</u>	<u>\$ (501,879)</u>	<u>\$ 184,273</u>
Balance at December 31, 2022	37,656,037	4	532,499	(281)	(264,993)	267,229
Vesting of restricted shares	513,036	—	—	—	—	—
Stock-based compensation	—	—	9,834	—	—	9,834
Issuance of common stock under share-based compensation arrangements	49,277	—	485	—	—	485
Issuance of common stock in connection with underwritten public offering, net	9,200,000	1	107,749	—	—	107,750
Unrealized loss on marketable securities	—	—	—	(65)	—	(65)
Pension and other postemployment benefits	—	—	—	3	—	3
Net loss	—	—	—	—	(86,606)	(86,606)
Balance at September 30, 2023	<u>47,418,350</u>	<u>\$ 5</u>	<u>\$ 650,567</u>	<u>\$ (343)</u>	<u>\$ (351,599)</u>	<u>\$ 298,630</u>

See accompanying notes.

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

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities		
Net loss	\$ (113,320)	\$ (86,606)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,400	450
Stock-based compensation	16,305	9,834
Amortization of operating lease right-of-use assets	944	982
Impairment of long-lived assets	8,235	—
Amortization of debt discount	321	410
Issuance (payment) of PIK interest debt	(634)	375
Acquired in-process research and development	15,325	—
Net accretion/amortization of premiums and discounts on marketable securities	(3,932)	(1,876)
Loss on extinguishment of debt	1,853	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets (includes related party amounts of \$0 and \$77, respectively)	(665)	2,427
Accounts payable, accrued expenses and other long-term liabilities (includes related party amounts of \$39 and \$(281), respectively)	(15,325)	4,459
Accrued interest	(134)	73
Operating lease right-of-use assets and liabilities	(976)	4,295
Net cash used in operating activities	(90,603)	(65,177)
Cash flows from investing activities		
Cash paid for purchased in-process research and development	(15,325)	—
Purchases of property and equipment	(412)	(10,010)
Purchases of marketable securities	(155,299)	(129,097)
Proceeds from sales or maturities of marketable securities	160,545	15,000
Net cash used in investing activities	(10,491)	(124,107)
Cash flows from financing activities		
Proceeds from issuance of common stock under share-based compensation arrangements	790	485
Proceeds from issuance of at-the-market offering, net	14,887	—
Repayment of long-term debt, including fees	(27,497)	—
Proceeds from issuance of common stock in underwritten public offering, net of issuance costs	—	108,100
Proceeds from issuance of long-term debt, net of issuance costs	—	9,800
Net cash provided by (used in) financing activities	(11,820)	118,385
Net decrease in cash, cash equivalents and restricted cash	(112,914)	(70,899)
Cash, cash equivalents and restricted cash—beginning of period	218,309	281,032
Cash, cash equivalents and restricted cash—end of period	\$ 105,395	\$ 210,133
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ 925	\$ 1,121
Supplemental disclosure of noncash investing and financing activities		
Unpaid underwritten public offering costs	\$ —	\$ 350
Unpaid property and equipment purchases	\$ —	\$ 171
Accreted final interest payment fees	\$ —	\$ 339

See accompanying notes.

HilleVax, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Organization

Organization

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

Liquidity and Capital Resources

From inception to September 30, 2024, the Company has devoted substantially all of its efforts to organizing and staffing the Company, business planning, raising capital, in-licensing its initial vaccine candidate, HIL-214, preparing for and managing its clinical trials of HIL-214, and providing other general and administrative support for these operations. The Company has a limited operating history, has never generated any revenue, and the sales and income potential of its business is unproven. The Company has incurred net losses and negative cash flows from operating activities since its inception and expects to continue to incur net losses into the foreseeable future as it continues the development and potential commercialization of its norovirus vaccine candidates. From inception to September 30, 2024, the Company has funded its operations through the issuance of convertible promissory notes, commercial bank debt, the sale of 13,529,750 shares of common stock for net proceeds of approximately \$209.5 million in its initial public offering ("IPO") which closed in May 2022, and the sale of 9,200,000 shares of common stock for net proceeds of approximately \$107.8 million in its underwritten public offering which closed in September 2023 (see Note 10).

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

2. Summary of Significant Accounting Policies

Basis of Presentation

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

Unaudited Interim Financial Information

The unaudited condensed consolidated financial statements as of September 30, 2024, and for the three and nine months ended September 30, 2024 and 2023, 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, 2023 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, 2023, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 20, 2024.

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. 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 Measurements

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

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

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

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

Cash and Cash Equivalents

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

Restricted Cash

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

Marketable Securities

Marketable securities represent holdings of available-for-sale marketable debt securities in accordance with the Company's investment policy. The Company has classified its investments with maturities beyond one year as current, based on their highly liquid nature and because such marketable securities represent the investment of cash that is available for current operations.

Investments in marketable securities are recorded at fair value, with any unrealized gains and losses reported within accumulated other comprehensive income (loss) as a separate component of stockholders' equity (deficit) until realized, a determination is made that an other-than-temporary decline in market value has occurred or until the security has experienced a credit loss. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion, together with interest on securities sold, is determined based on

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

Concentrations of Credit Risk

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

Property and Equipment, Net

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

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

Repairs and maintenance costs are charged to expense as incurred.

Leases

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

Impairment of Long-Lived Assets

The Company reviews long-lived assets, such as property and equipment and operating lease right-of-use assets, for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. During the nine months ended September 30, 2024, the Company's stock price and resulting market capitalization experienced a significant decline. Accordingly, the Company assessed its long-lived assets, including property and equipment and operating lease right-of-use assets, for impairment. 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. As a result of its fair value analysis, the Company recorded a \$8.2 million impairment charge on its long-lived assets for the nine months ended September 30, 2024. The Company did not record any impairment charges for the three months ended September 30, 2024.

Research and Development Expenses and Accruals

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

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

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

In-Process Research and Development

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

Patent Costs

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

Stock-Based Compensation

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

Benefit plans

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

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

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the 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. For the three and nine months ended September 30, 2024 and 2023, comprehensive loss included gains and losses on the Company's pension benefit obligation and unrealized gains and losses on marketable securities.

Segment Reporting

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

Net Loss Per Share

Basic net loss per share is computed by dividing the consolidated net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. The Company has excluded weighted-average unvested shares of 474,744 shares, 1,149,612 shares, 642,165 shares, and 1,318,737 shares from the basic weighted-average number of common shares outstanding for the three months ended September 30, 2024 and 2023 and nine months ended September 30, 2024 and 2023, respectively. Diluted net loss per share is computed by dividing the consolidated net loss by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. Potentially dilutive common stock equivalents are comprised of unvested common stock, common stock options, and contingently issuable shares under the Company's employee stock purchase plan. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as inclusion of the potentially dilutive common stock equivalents would be antidilutive.

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

	September 30,	
	2024	2023
Common stock options	5,021,708	3,770,701
Unvested common stock	1,713,318	1,742,090
ESPP shares	—	16,767
Total potentially dilutive shares	<u>6,735,026</u>	<u>5,529,558</u>

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

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

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740). The amendments in this update expand income tax disclosure requirements, including additional information pertaining to the rate reconciliation, income taxes paid, and other disclosures. This update is effective for annual periods beginning after December 15, 2024. The adoption

of this standard is not expected to have a material impact on the Company's condensed consolidated financial statements.

3. Fair Value Measurements

The Company's cash, cash equivalents, marketable securities, and restricted cash are carried at fair value, determined according to the fair value hierarchy discussed in Note 2. The carrying values of the Company's prepaid expenses and other current assets, accounts payable, and accrued liabilities, approximate fair value due to their short maturities. The estimated fair value of the Company's long-term debt approximated the carrying amount given its floating interest rate basis.

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

	Fair Value Measurements at September 30, 2024 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents				
Money market funds	\$ 98,273	\$ 98,273	\$ —	\$ —
Marketable securities:				
U.S. treasury notes	46,818	46,818	—	—
U.S government agency bonds	38,728	—	38,728	—
Total	<u>\$ 183,819</u>	<u>\$ 145,091</u>	<u>\$ 38,728</u>	<u>\$ —</u>

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

U.S. government money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy.

As of September 30, 2024, the Company's marketable securities consisted of U.S. Treasury notes which were valued based on Level 1 inputs and agency bonds which were valued based on Level 2 inputs. In determining the fair value of its agency bonds, the Company relied on quoted prices for similar securities in active markets or other inputs that are observable or can be corroborated by observable market data.

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

4. Marketable Securities

The following tables present the fair value of available-for-sale marketable debt securities by type of security as follows (in thousands):

	September 30, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities:				
U.S. treasury notes	\$ 46,808	\$ 11	\$ (1)	\$ 46,818
U.S. government agency bonds	38,689	39	—	38,728
Total	<u>\$ 85,497</u>	<u>\$ 50</u>	<u>\$ (1)</u>	<u>\$ 85,546</u>

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

At September 30, 2024 and December 31, 2023, all available-for-sale marketable securities had contractual maturities of less than one year.

As of September 30, 2024, the Company reviewed its investment portfolio to assess the unrealized losses on its available-for-sale investments. In making this assessment, the Company considered the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors. The Company also evaluated whether it intended to sell the security and whether it was more likely than not that the Company would be required to sell the security before recovering its amortized cost basis. The Company determined no portion of the unrealized losses relate to a credit loss. There have been no impairments of the Company's assets measured and carried at fair value during the three and nine months ended September 30, 2024.

5. Other Balance Sheet Details

Property and Equipment

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

	September 30, 2024	December 31, 2023
Computer equipment	\$ 103	\$ 103
Furniture and equipment	377	377
Leasehold improvements	8,845	11,964
Lab equipment	2,730	2,116
Construction in progress	—	338
Total property and equipment, at cost	<u>12,055</u>	<u>14,898</u>
Less accumulated depreciation	2,280	880
Property and equipment, net	<u>\$ 9,775</u>	<u>\$ 14,018</u>

Depreciation expense for the three and nine months ended September 30, 2024 was \$0.5 million and \$1.4 million, respectively. Depreciation expense for each of the three and nine months ended September 30, 2023 was \$0.4 million and \$0.5 million, respectively.

Gross asset balances in the table above reflect \$3.1 million of long-lived asset impairment described in Note 2 above.

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Accrued external research and development costs	\$ 7,974	\$ 12,665
Accrued payroll and payroll-related costs	587	5,233
Accrued professional costs	213	498
Other	308	157
Total accrued expenses	<u>\$ 9,082</u>	<u>\$ 18,553</u>

Cash, Cash Equivalents and Restricted Cash

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

	September 30, 2024	December 31, 2023
Cash and cash equivalents	\$ 103,764	\$ 216,678
Restricted cash	1,631	1,631
Total cash, cash equivalents and restricted cash	<u>\$ 105,395</u>	<u>\$ 218,309</u>

6. Leases

Operating Leases

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

In March 2022, the Company entered into a lease for office and laboratory space located in Boston, Massachusetts (as amended, the "Boston Lease"), which it determined was an operating lease at the inception of the lease contract. The Boston Lease commenced in April 2022 with base rental payments beginning in January 2023. The Boston Lease includes certain tenant improvement allowances for the reimbursement of \$6.2 million of costs incurred by the Company, and an option for the Company to extend the lease for a period of five years, which the Company is not reasonably certain to exercise. The Company determined that it owns the leasehold improvements related to the Boston Lease and, as such, reflected the \$6.2 million lease incentive as a reduction of the rental payments used to measure the operating lease liability, and, in turn, the operating lease right-of-use asset as of the lease commencement date in April 2022. Between the lease commencement date and September 30, 2024, the Company recorded increases of \$6.2 million to the operating lease liability as and when such lease incentives were received from the landlord. Under the terms of the Boston Lease, the Company provided the lessor with an irrevocable standby letter of credit secured by restricted cash in the amount of \$1.6 million.

The Company completed an evaluation of the carrying value of its long-lived assets, including its operating lease right-of-use asset. This process includes evaluating the estimated remaining lives, significant changes in the use, and potential impairment charges related to its long-lived assets. The Company used market participant assumptions to determine the fair value of the operating lease right-of-use asset. Based on its evaluation, the Company determined that the operating lease right-of-use asset was impaired and recorded a \$5.1 million charge during the nine months ended September 30, 2024.

The following table summarizes operating lease expense for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Lease expense:				
Operating lease expense	\$ 827	\$ 780	\$ 2,409	\$ 2,339

The Company incurred an immaterial amount of expense related to short-term leases and variable lease costs during the three and nine months ended September 30, 2024 and 2023.

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

	September 30, 2024	December 31, 2023
Other information:		
Weighted-average remaining lease term	8.20	9.00
Weighted-average discount rate	7.4 %	7.4 %

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

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

	September 30, 2024
Cash paid for amounts included in the measurement of operating lease liabilities (operating cash flows)	\$ 2,689

At September 30, 2024, the future minimum noncancelable operating lease payments were as follows (in thousands):

	September 30, 2024
Years ending December 31:	
2024	897
2025	3,692
2026	3,787
2027	3,860
2028	3,974
Thereafter	17,101
Total undiscounted operating lease payments	33,311
Present value adjustment	(8,338)
Operating lease liability	24,973
Less current portion of operating lease liability	3,546
Operating lease liability, net of current portion	\$ 21,427

7. Related Party Transactions

Frazier Life Sciences X, L.P. or its affiliates ("Frazier") is a principal stockholder of the Company and is represented on the Company's board of directors. From January 8, 2019 (inception) to September 30, 2024, 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. The Company did not incur any material shared operating expenses for the three and nine months ended September 30, 2024 and 2023.

In connection with the Takeda License (as defined and described in Note 8), Takeda became a related party stockholder with representation on the Company's board of directors. The Company and Takeda are party to a TSA (as defined and described in Note 8) under which the Company is obligated to pay Takeda for certain services, including pass-through costs, related to research and development and regulatory assistance services, oversight and management of ongoing clinical and research studies, and maintenance of third-party vendor contracts. For the three months ended

September 30, 2024 and 2023 and nine months ended September 30, 2024 and 2023, the Company incurred \$36,000, \$55,000, \$0.1 million and \$0.3 million, respectively, of research and development expenses for Takeda's services. As of September 30, 2024 and December 31, 2023, the Company had \$0.1 million and \$33,000, respectively, of accounts payable and accrued expenses due to Takeda. See Note 8 for further information regarding the Company's related party transactions with Takeda.

8. Commitments and Contingencies

License Agreement with Takeda

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

The Company is obligated to pay Takeda \$7.5 million upon the achievement of a specified development milestone, up to an aggregate of \$150.0 million in sales milestones upon the achievement of specified annual sales levels of HIL-214 products in the Territory, and tiered high single-digit to low-teen percentage royalties on net sales of HIL-214 products in the Territory, subject to specified offsets and reductions. Takeda has agreed to pay the Company tiered mid-single digit to low-double digit percentage royalties on net sales of HIL-214 products in Japan, subject to specified offsets and reductions. Royalties will be payable, on a product-by-product and country-by-country basis from the first commercial sale of such product in such country, until the latest of expiration of the licensed patents covering the applicable product, expiration of regulatory exclusivity in such country, or 20 years following first commercial sale of such product in such country. The obligations related to contingent payments are recognized in the accompanying condensed consolidated financial statements when the contingency is resolved and the consideration is paid or becomes payable. As of September 30, 2024, none of the remaining contingent payments were due or payable.

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

The Company did not make any milestone payments to Takeda during the three and nine months ended September 30, 2024 and 2023.

Transitional Services Agreement with Takeda

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

License Agreement with Kangh

On January 8, 2024, the Company entered into an exclusive license agreement with Chengdu Kanghua Biological Products Co., Ltd. ("Kangh"), for rights to Kangh's hexavalent virus-like particle vaccine candidate for norovirus (the "Kangh License"), referred to by the Company as HIL-216, outside of Greater China (the "Territory").

In consideration of the Kangh License, the Company has an upfront payment amount of \$15.0 million. In addition, the Company has the potential to pay Kangh up to \$255.5 million upon achieving certain development and sales milestones. Kangh is also eligible to receive a single-digit tiered royalty on net sales outside of Greater China.

The acquisition of the Kangh License has been accounted for as an asset acquisition as substantially all of the fair value is concentrated in a group of similar assets. In March 2024, the Company paid Kangh an upfront amount of \$15.0 million for the Kangh License, which has no alternative future use, and was recorded as in-process research and development in the Company's consolidated statement of operations for the nine months ended September 30, 2024.

401(k) Plan

The Company established a defined-contribution plan under Section 401(k) of the Internal Revenue Code (the 401(k) Plan). The 401(k) Plan covers all eligible employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. During the year ended December 31, 2022, the Company began matching contributions equal to 100% of the employee's contributions, subject to a maximum of 4% of eligible compensation. The Company made matching contributions of \$0.1 million, \$0.1 million, \$0.6 million, and \$0.5 million during the three and nine months ended September 30, 2024 and 2023, respectively.

Contingencies

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

9. Long-Term Debt

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

On June 16, 2023, the Company entered into a First Amendment to Loan and Security Agreement (the "First Amendment") with Hercules and the Lenders party thereto, which amended the Existing Loan Agreement. In connection with the First Amendment, the Company borrowed \$10.0 million under Term Loan Tranche 1. Additionally, the First Amendment, among other things, amended the following: (i) with respect to the remaining \$5.0 million under Term Loan Tranche 1, modified the period during which the Company may borrow thereunder to start on December 1, 2023 and end May 31, 2024 (or such earlier date if Lenders elect in their sole discretion), (ii) with respect to Term Loan Tranche 2, modified the period during which the Company may borrow thereunder to start on December 1, 2023 and end May 31, 2024 (or such earlier date if Lenders elect in their sole discretion) and (iii) with respect to Term Loan Tranche 3, (a) added as a new condition to borrow thereunder that (x) the Company's Phase 2b clinical trial evaluating the safety, immunogenicity and efficacy of HIL-214 in infants ("NEST-IN1") has achieved the protocol-specified primary efficacy endpoint and (y) HIL-214 has demonstrated acceptable safety results in the NEST-IN1 clinical trial, and, as a result, the Company supports the initiation of a Phase 3 registrational trial as the next immediate step in the development of HIL-214 (the "Tranche 3 Milestone") and (b) modified the period during which the Company may borrow thereunder to start on the date the Company achieves the Tranche 3 Milestone and end on the earlier of (x) June 15, 2024 and (y) 30 days following the date the Company achieves the Tranche 3 Milestone. The First Amendment was accounted for as a debt modification; as such, the financing costs of \$0.2 million were reflected as additional debt discount and is amortized as an adjustment to interest expense over the term of the First Amendment.

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

The Term Loans bear (a) cash interest at a floating rate of the higher of (i) the Wall Street Journal prime rate (or 5.00% if less) plus 1.05%, or (ii) 4.55% (interest rate of 6.05% as of September 30, 2024), and (b) additional interest ("PIK Interest") at a per annum rate equal to 2.85%, with such interest being added to the outstanding principal balance of the Term Loans on a monthly basis. The monthly payments consist of interest-only through June 1, 2025 or, if prior to April

30, 2025, the Company achieves the Tranche 3 Milestone, subject to reasonable verification by Hercules, through June 1, 2026. Subsequent to the interest-only period, the Term Loans will be payable in equal monthly installments of principal, plus accrued and unpaid interest, through the maturity date of May 1, 2027. In addition, the Company is obligated to pay a final payment fee equal to the greater of (i) \$2.145 million and (ii) 7.15% of the original principal amount of the Term Loans (which is \$2.1 million as of September 30, 2024). The final payment fee is recorded as a debt discount amortized over the life of the debt. The Company may elect to prepay all or a portion of the Term Loans prior to maturity, subject to a prepayment fee of up to 0.5% 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.

During the three months ended September 30, 2024, the Company recognized an immaterial amount of interest expense related to the Term Loans using the effective interest method. During the nine months ended September 30, 2024, the Company recognized interest expense of \$1.5 million related to the Term Loans using the effective interest method. Included in such expense was \$0.3 million related to accretion of the final payment fee to other long-term liabilities, \$0.4 million of PIK interest, \$0.7 million of coupon interest, and an immaterial amount of debt discount amortization.

On July 19, 2024, the Company repaid in full the entire \$26.2 million of outstanding principal and interest under the Loan Agreement. The Company made a final payment of \$28.5 million, including a final payment fee and prepayment fee of \$2.3 million. The loss on extinguishment of the debt of approximately \$1.9 million was recorded as interest expense during the three and nine months ended September 30, 2024. In connection with the repayment, the Loan Agreement and the other loan documents associated therewith were terminated and the Lenders' security interests in the Company's assets and property were released.

10. Stockholders' Equity

Initial Public Offering

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

At-the-Market-Offering

On May 12, 2023, the Company entered into an At-the-Market Equity Offering Sales Agreement (the "Sales Agreement") with Stifel, Nicolaus & Company, Incorporated (the "Agent"), pursuant to which the Company may offer and sell shares of the Company's common stock having an aggregate offering price of up to \$100.0 million from time to time, in "at the market" offerings through the Agent. Sales of the shares of common stock, if any, will be made at prevailing market prices at the time of sale, or as otherwise agreed with the Agent. The Agent will receive a commission from the Company of up to 3.0% of the gross proceeds of any shares of common stock sold under the Sales Agreement. The Company is not obligated to sell, and the Agent is not obligated to buy or sell, any shares of common stock under the Sales Agreement. During the three months ended September 30, 2024, the Company sold 1,016,950 shares of common stock for total net proceeds of approximately \$14.9 million, after deducting commission fees and offering expenses.

Underwritten Public Offering

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

2021 Equity Incentive Plan

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

2022 Incentive Award Plan

In April 2022, the Company's board of directors and stockholders approved the 2022 Incentive Award Plan (the "2022 Plan," and together with the 2021 Plan, the "Plans") under which the Company may grant stock options, restricted stock, dividend equivalents, restricted stock units, stock appreciation rights, and other stock or cash-based awards to its employees, consultants and directors. The 2022 Plan became effective in connection with the Company's IPO and will remain in effect until the tenth anniversary of its effective date, which will be April 28, 2032, unless earlier terminated by the Company's board of directors. The number of shares of the Company's common stock initially available for issuance under awards granted pursuant to the 2022 Plan was the sum of (1) 4,900,000 shares of the Company's common stock, plus (2) 216,849 shares remaining available for issuance under the 2021 Plan as of the effective date of the 2022 Plan, plus (3) any shares subject to outstanding awards under the 2021 Plan as of the effective date of the 2022 Plan that become available for issuance under the 2022 Plan thereafter in accordance with its terms. The number of shares initially available for issuance will be increased by an annual increase on January 1 of each calendar year ending in and including 2032, equal to the lesser of (1) 5% of the shares of common stock outstanding on the final day of the immediately preceding calendar year and (2) such smaller number of shares as determined by the Company's board of directors. As of September 30, 2024, 9,640,604 shares were reserved for issuance under the 2022 Plan, of which 3,945,845 shares remained available for future issuance.

2022 Employee Stock Purchase Plan

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

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

	Number of Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance at December 31, 2023	3,896,061	\$ 13.89	8.82	\$ 11,826
Granted	2,101,895	14.85		
Exercised	(49,675)	7.72		
Cancelled	(926,573)	14.41		
Balance at September 30, 2024	<u>5,021,708</u>	\$ 14.25	7.92	\$ —
Vested and expected to vest at September 30, 2024	<u>5,021,708</u>	\$ 14.25	7.92	\$ —
Exercisable at September 30, 2024	<u>1,908,177</u>	\$ 13.31	6.43	\$ —

Stock-Based Compensation Expense

The fair value of common stock is based on the closing price as reported on the date of grant on the primary stock exchange on which the Company's common stock is traded. The assumptions used in the Black-Scholes option pricing model to determine the fair value of stock option grants were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Risk-free interest rate	—	4.1%–4.6%	3.9%–4.7%	3.5%–4.6%
Expected volatility	—	94.5%–95.1%	95.1%–99.1%	91.7%–95.9%
Expected term (in years)	—	6.1	5.5–6.1	5.5–6.1
Expected dividend yield	—	0%	0%	0%

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

Expected volatility. Given the Company's limited historical stock price volatility data, the expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

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

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 2,402	\$ 1,894	\$ 8,298	\$ 4,710
General and administrative	2,648	2,052	8,007	5,124
Total	\$ 5,050	\$ 3,946	\$ 16,305	\$ 9,834

There were no option grants during the three months ended September 30, 2024. The weighted average grant date fair value per share of option grants for the three months ended September 30, 2023 was \$13.69. The weighted average grant date fair value per share of option grants for the nine months ended September 30, 2024 and 2023 was \$11.70 and \$17.68, respectively. As of September 30, 2024, total unrecognized stock-based compensation cost related to stock options was approximately \$31.9 million, which is expected to be recognized over a remaining weighted-average period of approximately 2.6 years.

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

	Number of Unvested Shares	Weighted Average Grant-Date Fair Value
Balance at December 31, 2023	1,571,716	\$ 8.474
Shares granted	1,036,450	15.019
Shares forfeited	(198,963)	15.643
Share vested	(695,885)	4.987
Balance at September 30, 2024	1,713,318	13.043

The Company did not issue any shares of restricted common stock during the three months ended September 30, 2024 and 2023. The Company issued shares of restricted common stock during the nine months ended September 30, 2024 and 2023, which consisted only of restricted stock units. The weighted average grant date fair value per share of restricted common stock grants for the nine months ended September 30, 2024 and 2023 was \$15.02 and \$18.00, respectively. As

of September 30, 2024, total unrecognized stock-based compensation cost related to restricted stock was approximately \$18.0 million, which is expected to be recognized over a remaining weighted-average period of approximately 2.9 years. For accounting purposes, unvested shares of restricted common stock are not considered outstanding until they vest. As of September 30, 2024 and December 31, 2023, the Company had no material repurchase liability related to the unvested shares in the table above.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following:

	September 30, 2024
Common stock options outstanding	5,021,708
Shares available for issuance under the Plans	3,945,845
Shares available for issuance under the ESPP	1,169,616
	10,137,169

11. Subsequent Events

On October 15, 2024, the Company completed a workforce reduction of approximately 15 employees, constituting approximately 25% of the Company’s workforce. The Company currently estimates that it will incur charges associated with the workforce reduction of approximately \$1.3 million primarily related to employee severance payments, benefits and related termination costs. The Company expects that the reduction in force will be substantially complete with the majority of related charges recognized in the fourth quarter of 2024. The estimates of the charges and expenditures that the Company expects to incur in connection with the workforce reduction, and the timing thereof, are subject to several assumptions and the actual amounts incurred may differ materially from these estimates. In addition, the Company may incur other charges or cash expenditures not currently contemplated due to unanticipated events that may occur, including in connection with the implementation of the workforce reduction.

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, 2023 and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the Securities and Exchange Commission (SEC) on March 20, 2024 (the 2023 Form 10-K).

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 clinical trials for our product candidates, the timing and likelihood of regulatory filings and approvals for our product candidates, our ability to commercialize our product candidates, if approved, plans and objectives of management for future operations and future results of anticipated product development efforts, are forward-looking statements. 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 virus-like particle (VLP) based vaccine candidate for the prevention of moderate-to-severe acute gastroenteritis (AGE) caused by norovirus infection. It is estimated that norovirus causes nearly 700 million cases of illness and more than 200,000 deaths worldwide per year, as well as significant additional economic and social burden. To date, HIL-214 has been studied in nine clinical trials conducted by Takeda and LigoCyte, which collectively generated safety data from more than 4,500 subjects and immunogenicity data from more than 2,200 subjects, including safety and immunogenicity data from more than 800 pediatric subjects. A randomized, placebo-controlled Phase 2b field efficacy trial enrolled 4,712 adult subjects, and HIL-214 was well tolerated and demonstrated clinical proof of concept in preventing moderate-to-severe cases of AGE from norovirus infection. In September 2021, an open investigational new drug (IND) application was transferred to us from Takeda, under which we initiated a Phase 2b clinical trial, NEST-IN1 (Norovirus Efficacy and Safety Trial in Infants, or NOR-212), in May 2022 to evaluate the safety, immunogenicity, and efficacy of HIL-214 in infants. In May 2022, we completed enrollment of the prespecified 200 subject run-in for NEST-IN1. We resumed enrollment in NEST-IN1 in August 2022, following the prespecified safety assessment by the clinical trial’s data monitoring committee. In December 2022, we reported positive interim immunogenicity results for the first 200 subjects of NEST-IN1. In July 2024, we reported top-line data from NEST-IN1. The study did not meet its primary endpoint of efficacy against moderate or severe AGE events due to GI.1 or GII.4 norovirus genotypes. No clinical benefit was observed across secondary endpoints. HIL-214 exhibited a safety and immunogenicity profile consistent with what was observed in the prespecified analysis of the first 200 subjects in NEST-IN1 and in previously reported studies. We plan to discontinue further development of HIL-214 and are exploring the potential for continued development of our other norovirus vaccine candidates, as well as business development-related activities for these vaccine candidates and other strategic alternatives. On July 31, 2024 and October 15, 2024, we announced workforce reductions of approximately 41 and 15 employees, respectively, constituting approximately 55% of our workforce. We currently estimate that it will incur charges associated with the workforce reduction of approximately \$4.7 million primarily related to employee severance payments, benefits and related termination costs. We expect that the reduction in force that occurred in October 2024 will be substantially complete with the majority of related charges recognized in the fourth quarter of 2024. The estimates of the

charges and expenditures that we expect to incur in connection with the workforce reduction, and the timing thereof, are subject to several assumptions and the actual amounts incurred may differ materially from these estimates. In addition, we may incur other charges or cash expenditures not currently contemplated due to unanticipated events that may occur, including in connection with the implementation of the workforce reduction.

We commenced our operations in 2019 and have devoted substantially all of our resources to date to organizing and staffing our company, business planning, raising capital, in-licensing intellectual property related to our initial vaccine candidate, HIL-214, preparing for and managing our clinical trials of HIL-214, and providing other general and administrative support for our operations. We have funded operations to date primarily through the issuance of convertible promissory notes, commercial bank debt, the sale of common stock in our initial public offering (IPO) which closed in May 2022 and the sale of common stock in our underwritten public offering which closed in September 2023. As of September 30, 2024, we had cash, cash equivalents and marketable securities of \$189.3 million. From inception to September 30, 2024, we raised aggregate gross proceeds of \$137.2 million from the issuance of convertible promissory notes, we completed our IPO in May 2022, whereby we sold 13,529,750 shares of common stock at a public offering price of \$17.00 per share, for net proceeds of approximately \$209.5 million, after deducting underwriting discounts, commissions and offering costs of approximately \$20.5 million, we borrowed \$25.0 million in commercial bank debt and we completed an underwritten public offering in September 2023, whereby we sold 9,200,000 shares of our common stock, which included the exercise in full by the underwriters of their option to purchase 1,200,000 shares, at a public offering price of \$12.50 per share, for total net proceeds of approximately \$107.8 million.

We do not have any products approved for sale, have not generated any revenue and have incurred net losses since our inception. Our net losses for the three months ended September 30, 2024 and 2023 and nine months ended September 30, 2024 and 2023 were \$25.8 million, \$31.8 million, \$113.3 million and \$86.6 million, respectively. As of September 30, 2024, we had an accumulated deficit of \$501.9 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical development activities, other research and development activities and pre-commercialization activities.

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

Financial Operations Overview

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

License Agreement with Takeda

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

commercially reasonable efforts to develop and commercialize HIL-214 products in the Territory, and to seek regulatory approval for such products throughout the world.

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

Transitional Services Agreement with Takeda

As contemplated by the Takeda License, on December 17, 2021, we and Takeda entered into a Transitional Services Agreement (the TSA). Pursuant to the TSA, Takeda has agreed to provide, on a transitional basis following the effective date of the Takeda License, certain services related to research and development and regulatory assistance services, oversight and management of ongoing clinical and research studies, and maintenance of certain third-party vendor contracts. In consideration for the services provided under the TSA, we have agreed to pay certain specified amounts to Takeda in cash for such services and certain pass-through costs. For the three and nine months ended September 30, 2024 and 2023, we incurred \$36,000, \$29,000, \$0.1 million, and \$0.2 million, respectively, of research and development expenses for Takeda's services.

License Agreement with Kangh

On January 8, 2024, we and Chengdu Kanghua Biological Products Co., Ltd. (Kangh) entered into an exclusive license agreement (the Kangh License) for rights to Kangh's hexavalent virus-like particle vaccine candidate for norovirus, referred to by us as HIL-216, outside of Greater China (the Territory). We will be responsible, at our cost, for the development, manufacture and commercialization of HIL-216 products in the Territory. We are obligated to use commercially reasonable efforts to develop and commercialize HIL-216 products in the Territory, and to seek regulatory approval for such products throughout the Territory.

In consideration of the Kangh License, we have paid an upfront amount of \$15.0 million. In addition, we have the potential to pay Kangh up to \$255.5 million upon achieving certain development and sales milestones. Kangh is also eligible to receive a single-digit tiered royalty on net sales outside of Greater China.

Components of Results of Operations

Operating Expenses

Research and Development

During 2024 and 2023, our research and development expenses have primarily been related to the development of HIL-214. Research and development expenses are recognized as incurred, and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Research and development expenses include:

- salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in research and development efforts;

- external research and development expenses incurred under agreements with CROs and consultants to conduct and support our planned preclinical studies and clinical trials of our norovirus vaccine candidates; and
- costs related to manufacturing our vaccine candidates for our planned preclinical studies and clinical trials.

If we continue the development of our norovirus vaccine candidates, we plan to substantially increase our research and development expenses for the foreseeable future. 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 our norovirus vaccine candidates or any other vaccine candidates due to the inherently unpredictable nature of clinical and preclinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast whether our norovirus vaccine candidates or any other vaccine candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

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

- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects;
- the number of subjects that participate in the trials;
- the number of doses evaluated in the trials;
- the costs and timing of manufacturing our norovirus vaccine candidates and placebo for use in our trials;
- the drop-out or discontinuation rates of clinical trial subjects;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the phase of development of the vaccine candidate;
- the impact of any interruptions to our operations or to those of the third parties with whom we work due to any future pandemic or other disease outbreaks or geopolitical events or war; and
- the safety, purity, potency, immunogenicity and efficacy of the vaccine candidate.

In-Process Research and Development

In-process research and development expenses for the nine months ended September 30, 2024 relate to the Kangh License, and include an aggregate \$15.0 million upfront payment for exclusive use of the license.

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.

Impairment Charges

Impairment charges consist of an impairment loss on our long-lived assets.

Interest Income

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

Interest Expense

Interest expense consists of interest on our term loan facility, which was extinguished in July 2024.

Results of Operations

Comparison of the three months ended September 30, 2024 and 2023

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

	Three Months Ended September 30,		Change
	2024	2023	
Operating expenses:			
Research and development	\$ 20,165	\$ 27,308	\$ (7,143)
General and administrative	6,215	6,603	(388)
Total operating expenses	26,380	33,911	(7,531)
Loss from operations	(26,380)	(33,911)	7,531
Other income (expense):			
Interest income	\$ 1,353	1,690	(337)
Interest expense	(1,853)	(717)	(1,136)
Other income (expense)	1,057	1,123	(66)
Total other income	557	2,096	(1,539)
Net loss	\$ (25,823)	\$ (31,815)	\$ 5,992

Research and development expenses. Research and development expenses were \$20.2 million and \$27.3 million for the three months ended September 30, 2024 and 2023, respectively. The decrease of \$7.1 million primarily consisted of \$10.6 million related to clinical development expenses related to HIL-214, partially offset by an increase of \$2.4 million of personnel-related expenses, primarily related to charges associated with our workforce reduction in July 2024, and \$1.1 million of facility and other expenses.

General and administrative expenses. General and administrative expenses were \$6.2 million and \$6.6 million for the three months ended September 30, 2024 and 2023, respectively. The decrease of \$0.4 million primarily consisted of \$0.7 million of professional service and other expenses, partially offset by an increase of \$0.3 million of personnel-related expenses, primarily related to charges associated with our workforce reduction in July 2024.

Other income (expense). Other income of \$0.6 million for the three months ended September 30, 2024 primarily consisted of \$1.4 million of interest income on our cash, cash equivalents and marketable securities and \$1.1 million of other income primarily related to the accretion of discounts to maturity on our marketable securities, partially offset by \$1.9 million of interest expense on our term loan facility. Other income of \$2.1 million for the three months ended September 30, 2023 primarily consisted of \$1.7 million of interest income on our cash, cash equivalents and marketable securities and \$1.1 million of other income primarily related to the accretion of discounts to maturity on our marketable securities, partially offset by \$0.7 million of interest expense on our term loan facility.

Comparison of the nine months ended September 30, 2024 and 2023

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

	Nine Months Ended September 30,		Change
	2024	2023	
Operating expenses:			
Research and development	\$ 72,744	\$ 73,425	\$ (681)
In-process research and development	15,325	—	15,325
General and administrative	22,836	19,629	3,207
Impairment charges	8,235	—	8,235
Total operating expenses	119,140	93,054	26,086
Loss from operations	(119,140)	(93,054)	(26,086)
Other income (expense):			
Interest income	\$ 5,453	6,717	(1,264)
Interest expense	(3,318)	(1,666)	(1,652)
Other income (expense)	3,685	1,397	2,288
Total other income (expense)	5,820	6,448	(628)
Net loss	\$ (113,320)	\$ (86,606)	\$ (26,714)

Research and development expenses. Research and development expenses were \$72.7 million and \$73.4 million for the nine months ended September 30, 2024 and 2023, respectively. The decrease of \$0.7 million primarily consisted of \$13.8 million related to clinical development expenses related to HIL-214, partially offset by \$8.0 million of personnel-related expenses, primarily related to charges associated with our workforce reduction in July 2024, \$2.4 million of consulting expenses, \$1.5 million of facility expenses, and \$1.3 million of other expenses.

In-process research and development expenses. We had \$15.3 million of in-process research and development expenses for the nine months ended September 30, 2024 related to the Kangh License, which was entered into in 2024. We did not incur any in-process research and development expenses for the nine months ended September 30, 2023.

General and administrative expenses. General and administrative expenses were \$22.8 million and \$19.6 million for the nine months ended September 30, 2024 and 2023, respectively. The increase of \$3.2 million primarily consisted of \$2.6 million of personnel-related expenses, primarily related to charges associated with our workforce reduction in July 2024, and \$1.5 million of consulting and other expenses, partially offset by a decrease of \$0.9 million related to professional service expenses.

Impairment charges. Impairment charges of \$8.2 million for the nine months ended September 30, 2024 consisted of \$5.1 million of impairment charges on our right-of-use asset and \$3.1 million of impairment charges on our property and equipment, which was triggered by the decline in our market capitalization over the subsequent release of the top-line data from our NEST-IN1 clinical study in July 2024. We did not incur any impairment charges for the nine months ended September 30, 2023.

Other income (expense). Other income of \$5.8 million for the nine months ended September 30, 2024 primarily consisted of \$5.5 million of interest income on our cash, cash equivalents and marketable securities and \$3.7 million of other income primarily related to the accretion of discounts to maturity on our marketable securities, partially offset by \$3.3 million of interest expense on our term loan facility. Other income of \$6.4 million for the nine months ended September 30, 2023 primarily consisted of \$6.7 million of interest income on our cash, cash equivalents and marketable securities and \$1.4 million of other income primarily related to the accretion of discounts to maturity on our marketable securities, partially offset by \$1.7 million of interest expense on our term loan facility.

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 our norovirus vaccine candidates, and may never become profitable. We have funded our operations to date primarily through the issuance of convertible promissory notes, the net proceeds raised from our IPO, an underwritten public offering in September 2023 and borrowings under our term loan facility. As of September 30, 2024, we had cash, cash equivalents and marketable securities of \$189.3 million.

Term Loan Facility

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

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

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

The Term Loans bear (a) cash interest at a floating rate of the higher of (i) the Wall Street Journal prime rate (or 5.00% if less) plus 1.05%, or (ii) 4.55% (interest rate of 6.05% as of September 30, 2024), and (b) additional interest (PIK Interest) at a per annum rate equal to 2.85%, with such interest being added to the outstanding principal balance of the Term Loans on a monthly basis. The monthly payments consist of interest-only through June 1, 2025 or, if prior to April 30, 2025, we achieve the Tranche 3 Milestone, subject to reasonable verification by Hercules, through June 1, 2026. Subsequent to the interest-only period, the Term Loans will be payable in equal monthly installments of principal, plus accrued and unpaid interest, through the maturity date of May 1, 2027. In addition, we are obligated to pay a final payment fee equal to the greater of (i) \$2.145 million and (ii) 7.15% of the original principal amount of the Term Loans. We may elect to prepay all or a portion of the Term Loans prior to maturity, subject to a prepayment fee of up to 0.5% 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.

On July 19, 2024, we repaid in full all outstanding indebtedness and terminated all commitments and obligations under the Loan Agreement with Hercules. We made a final payment of \$28.5 million, including a final payment fee and prepayment fee of \$2.3 million, under the Loan Agreement. In connection with the repayment, the Loan Agreement and the other loan documents associated therewith were terminated and the Lenders' security interests in our assets and property were released.

At-the-Market-Offering

On May 12, 2023, we entered into an At-the-Market Equity Offering Sales Agreement (Sales Agreement) with Stifel, Nicolaus & Company, Incorporated (the Agent), under which we may, from time to time at prevailing market prices, sell shares of our common stock having an aggregate offering price of up to \$100.0 million in "at the market" offerings through the Agent. As of September 30, 2024, we sold an aggregate of 1,016,950 shares of common stock pursuant to the Sales Agreement for total net proceeds of approximately \$14.9 million.

Underwritten Public Offering

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

Funding Requirements

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to meet our anticipated cash requirements through at least the next 12 months. 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, preclinical studies and clinical trials of our norovirus vaccine candidates or other potential vaccine candidates we may choose to pursue in the future, including any modifications to clinical development plans based on feedback that we may receive from regulatory authorities;
- the costs and timing of manufacturing for our norovirus vaccine candidates and placebo to be used in preclinical studies and 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 our norovirus vaccine candidates or any other vaccine candidates;
- any delays and cost increases that may result from any future pandemic or other disease outbreak or geopolitical events or war;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional officers and clinical development and commercial personnel;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the timing and amount of the milestone, royalty or other payments we must make to Takeda and any future licensors;
- the costs and timing of establishing or securing sales and marketing capabilities if our norovirus vaccine candidates or other vaccine candidates are approved;

- our ability to receive recommendations from the ACIP or other foreign NITAGs, and achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- vaccine recipients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors; and
- costs associated with any products or technologies that we may in-license or acquire.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through equity offerings, 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):

	Nine Months Ended September 30,	
	2024	2023
Net cash provided by (used in):		
Operating activities	\$ (90,603)	\$ (65,177)
Investing activities	(10,491)	(124,107)
Financing activities	(11,820)	118,385
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ (112,914)</u>	<u>\$ (70,899)</u>

Operating Activities

Net cash used in operating activities of \$90.6 million for the nine months ended September 30, 2024 was primarily due to our net loss of \$113.3 million and a net change of \$17.1 million in our operating assets and liabilities, partially offset by \$39.8 million of noncash charges primarily related to \$16.3 million of stock-based compensation, \$15.3 million of acquired in-process research and development, \$8.2 million related to the impairment of long-lived assets, \$1.9 million related to loss on extinguishment of debt, \$1.4 million related to depreciation expense, \$0.9 million related to the amortization of operating lease right-of-use assets and \$0.3 million related to amortization of debt discount prior to loan payoff, partially offset by \$3.9 million related to net amortization of premiums and discounts on marketable securities and \$1.0 million related to the issuance (payment) of PIK interest debt. The net change in operating assets and liabilities was primarily due to a decrease of \$1.0 million related to operating lease right-of-use assets and liabilities, \$0.7 million in prepaid expenses and other current assets and \$15.3 million in accounts payable and accrued expenses in support of the growth in our operating activities.

Net cash used in operating activities of \$65.2 million for the nine months ended September 30, 2023 was primarily due to our net loss of \$86.6 million, partially offset by a net change of \$11.3 million in our operating assets and liabilities and \$10.2 million of noncash charges primarily related to \$9.8 million of stock-based compensation, \$1.0 million related to the amortization of operating lease right-of-use assets, \$0.5 million related to depreciation expense, \$0.4 million related to amortization of debt discount and \$0.4 million related to issuance of PIK interest debt, partially offset by \$1.9 million related to net amortization of premiums and discounts on marketable securities. The net change in operating assets and liabilities was primarily due to an increase of \$4.3 million related to operating lease liabilities due to leasehold improvement reimbursements, \$2.4 million in prepaid expenses and other current assets and \$4.5 million in accounts payable and accrued expenses in support of the growth in our operating activities.

Investing Activities

Net cash used in investing activities of \$10.5 million for the nine months ended September 30, 2024 was due to \$155.3 million in purchases of marketable securities, \$15.3 million in cash paid for purchased in-process research and development and \$0.4 million in purchases of property and equipment, partially offset by \$160.5 million in proceeds from sales or maturities of marketable securities.

Net cash used in investing activities of \$124.1 million for the nine months ended September 30, 2023 was due to \$129.1 million in purchases of marketable securities and \$10.0 million in purchases of property and equipment, partially offset by \$15.0 million in proceeds from sales or maturities of marketable securities.

Financing Activities

Net cash used in financing activities of \$11.8 million for the nine months ended September 30, 2024 was due to \$27.5 million related to the repayment of long-term debt including fees, partially offset by \$14.9 million of net proceeds from the issuance of common stock in our at-the-market offering and \$0.8 million in proceeds from the issuance of stock under our share-based compensation arrangements.

Net cash provided by financing activities of \$118.4 million for the nine months ended September 30, 2023 was due to \$108.1 million of net proceeds from the issuance of common stock in our underwritten public offering, \$9.8 million of net proceeds in borrowings under our term loan facility, \$0.3 million in proceeds from the issuance of stock under our stock purchase plan and \$0.2 million in proceeds from the exercise of common stock options.

Contractual Obligations and Commitments

As of September 30, 2024, 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 2023 Form 10-K.

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 September 30, 2024, 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 2023 Form 10-K.

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 \$1.235 billion, (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held

by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

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

Recent Accounting Pronouncements

See Item 1 of Part I, "Notes to Condensed Consolidated Financial Statements — Note 2 — Summary of Significant Accounting Policies" of this Quarterly Report.

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

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, 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

There have been no material changes to the risk factors disclosed in Part I, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2023, other than as set forth in Part II, Item 1A, "Risk Factors" of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024.

PART II

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds

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

There has been no material change in the planned use of proceeds from our IPO from that described in the prospectus for the IPO. As of September 30, 2024, we estimate that we have used approximately \$239.4 million of the proceeds from our IPO for general corporate purposes, including to fund the clinical development of our norovirus vaccine candidates.

Issuer Repurchases of Equity Securities.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Trading Arrangements

During the three months ended September 30, 2024, none of our officers or directors adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non Rule 10b5-1 trading arrangement."

Exhibit Index

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation of HilleVax, Inc.	8-K	5/3/22	3.1	
3.2	Amended and Restated Bylaws of HilleVax, Inc.	8-K	5/3/22	3.2	
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 With Embedded Linkbase Documents				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				X

* 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.

**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: November 7, 2024

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

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

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

I, Shane Maltbie, 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: November 7, 2024

By: _____ /s/ Shane Maltbie

Shane Maltbie
Chief Financial Officer
(Principal Financial and Accounting Officer)

