UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2023

OR

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

Commission File Number: 001-41365

HILLEVAX, INC.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

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

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

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

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

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

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

As of May 9, 2023, the registrant had 39,200,174 shares of common stock, $0.0001 par value per share, outstanding.

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 260,542	$ 279,401
Prepaid expenses and other current assets	9,317	11,212
Total current assets	269,859	290,613
Property and equipment, net	10,450	5,586
Operating lease right-of-use assets	18,999	19,359
Restricted cash	1,631	1,631
Other assets	22	22
Total assets	$ 300,961	$ 317,211
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable (includes related party amounts of $0 and $141, respectively)	$ 1,744	$ 4,744
Accrued expenses (includes related party amounts of $312 and $140, respectively)	17,412	8,210
Accrued interest	79	55
Current portion of operating lease liability	38	37
Total current liabilities	19,273	13,046
Operating lease liability, net of current portion	22,977	21,569
Long-term debt, net of debt discount	14,903	14,792
Other long-term liabilities	747	575
Total liabilities	57,900	49,982
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; authorized shares— 50,000,000 at March 31, 2023 and December 31, 2022; no shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; authorized shares— 500,000,000 at March 31, 2023 and December 31, 2022; issued shares—39,200,174 and 39,240,746 at March 31, 2023 and December 31, 2022, respectively; outstanding shares— 37,841,987 and 37,656,037 at March 31, 2023 and December 31, 2022, respectively	4	4
Additional paid-in capital	535,221	532,499
Accumulated other comprehensive loss	(282)	(281)
Accumulated deficit	(291,882)	(264,993)
Total stockholders' equity	243,061	267,229
Total liabilities and stockholders' equity	$ 300,961	$ 317,211

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 March 31,	
	2023	2022
Operating expenses:		
Research and development (includes related party amounts of $168 and $1,422, respectively)	$ 23,164	$ 6,211
In-process research and development - related party	—	2,500
General and administrative (includes related party amounts of $3 and $26, respectively)	5,795	2,603
Total operating expenses	28,959	11,314
Loss from operations	(28,959)	(11,314)
Other income (expense):		
Interest income	2,574	6
Interest expense (includes related party amounts of $0 and $529, respectively)	(449)	(2,064)
Change in fair value of convertible promissory notes (includes related party amounts of $0 and $4,378, respectively)	—	(17,073)
Change in fair value of warrant liabilities - related party	—	(37,424)
Other income (expense)	(55)	(18)
Total other income (expense)	2,070	(56,573)
Net loss	$ (26,889)	$ (67,887)
Other comprehensive loss:		
Pension and other postemployment benefits	(1)	—
Total comprehensive loss	$ (26,890)	$ (67,887)
Net loss per share, basic and diluted	$ (0.71)	$ (10.06)
Weighted-average shares of common stock outstanding, basic and diluted	37,753,522	6,748,668

See accompanying notes.

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at December 31, 2021	6,599,886	$ 1	$ 4,426	$ —	$ (105,184)	$ (100,757)
Vesting of restricted shares	297,564	—	—	—	—	—
Stock—based compensation	—	—	272	—	—	272
Net loss	—	—	—	—	(67,887)	(67,887)
Balance at March 31, 2022	6,897,450	1	4,698	—	(173,071)	(168,372)
Balance at December 31, 2022	37,656,037	4	532,499	(281)	(264,993)	267,229
Vesting of restricted shares	174,568	—	—	—	—	—
Stock—based compensation	—	—	2,642	—	—	2,642
Exercise of common stock options	11,382	—	80	—	—	80
Pension and other postemployment benefits	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	(26,889)	(26,889)
Balance at March 31, 2023	37,841,987	$ 4	$ 535,221	$ (282)	$ (291,882)	$ 243,061

See accompanying notes.

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

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (26,889)	$ (67,887)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1	—
Stock-based compensation	2,642	272
Change in fair value of convertible promissory notes (includes related party amounts of $0 and $4,378, respectively)	—	17,073
Change in fair value of warrant liabilities - related party	—	37,424
Amortization of operating lease right-of-use assets	360	13
Amortization of debt discount	126	—
Issuance of PIK interest debt	94	—
Acquired in-process research and development - related party	—	2,500
Loss on disposal of property and equipment	—	42
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,895	(339)
Accounts payable, accrued expenses and other long-term liabilities (includes related party amounts of $31 and $(3,402), respectively)	4,384	(1,868)
Accrued interest (includes related party amounts of $0 and $529, respectively)	24	2,064
Operating lease liabilities	1,409	(9)
Net cash used in operating activities	(15,954)	(10,715)
Cash flows from investing activities		
Cash paid for purchased in-process research and development	—	(2,500)
Purchases of property and equipment	(2,985)	—
Net cash used in investing activities	(2,985)	(2,500)
Cash flows from financing activities		
Payment of initial public offering costs	—	(99)
Proceeds from exercise of stock options	80	—
Net cash provided by (used in) financing activities	80	(99)
Net decrease in cash, cash equivalents and restricted cash	(18,859)	(13,314)
Cash, cash equivalents and restricted cash—beginning of period	281,032	124,566
Cash, cash equivalents and restricted cash—end of period	$ 262,173	$ 111,252
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 192	$ —
Supplemental disclosure of noncash investing and financing activities		
Unpaid initial public offering costs	$ —	$ 548
Unpaid property and equipment purchases	$ 3,453	$ —
Accreted final interest payment fees	$ 109	$ —

See accompanying notes.

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.

Forward Stock Split

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

Initial Public Offering

On May 3, 2022, the Company completed its initial public offering ("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 (see Note 8).

Liquidity and Capital Resources

From inception to March 31, 2023, 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 HIL-214. From inception to March 31, 2023, the Company has funded its operations through the issuance of convertible promissory notes, commercial bank debt and the sale of common stock in its IPO which closed in May 2022.

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities. 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 GmbH, a wholly-owned subsidiary formed in Zurich, Switzerland. The functional currency of both the Company and HilleVax GmbH is the U.S. dollar. The Company’s assets

and liabilities that are not denominated in the functional currency are remeasured into U.S. dollars at foreign currency exchange rates in effect at the balance sheet date except for nonmonetary assets, which are remeasured at historical foreign currency exchange rates in effect at the date of transaction. Net realized and unrealized gains and losses from foreign currency transactions and remeasurement are reported in other income (expense), in the condensed consolidated statements of operations and were not material for the periods presented. All intercompany transactions have been eliminated in consolidation.

Unaudited Interim Financial Information

The unaudited condensed consolidated financial statements as of March 31, 2023, and for the three months ended March 31, 2023 and 2022, 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, 2022 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, 2022, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 17, 2023.

Use of Estimates

The preparation of the Company's unaudited condensed consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's condensed consolidated financial statements and accompanying notes. The most significant estimates in the Company's unaudited condensed consolidated financial statements relate to accruals for research and development expenses, and the valuation of convertible promissory notes, warrant liabilities and various other equity instruments. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results could differ materially from those estimates and assumptions.

Fair Value Option

As permitted under Accounting Standards Codification ("ASC") 825, *Financial Instruments*, ("ASC 825"), the Company has elected the fair value option to account for its convertible promissory notes issued through May 2022, when the convertible promissory notes converted into equity in connection with the Company's IPO. In accordance with ASC 825, the Company recorded these convertible promissory notes at fair value with changes in fair value recorded in the condensed consolidated statements of operations. As a result of applying the fair value option, direct costs and fees related to the convertible promissory notes were recognized in earnings as incurred and not deferred.

Fair Value Measurements

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

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

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

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

The carrying amounts of the Company's financial instruments, including cash, cash equivalents and restricted cash, classified within the Level 1 designation discussed above, 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 Company has no financial assets measured at fair value on a recurring basis. None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

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 4).

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents 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 (generally 3 years). 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, for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. Fair value would be assessed using discounted cash flows or other appropriate measures of fair value. The Company has not recognized any impairment losses through March 31, 2023.

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 and employee stock purchase rights, recognized on a straight-line basis over the requisite service period for stock options 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 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 months ended March 31, 2023, comprehensive loss included gains and losses on the Company's pension benefit obligation. For the three months ended March 31, 2022, the Company's comprehensive loss was the same as its reported net loss.

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 1,492,789 shares and 2,476,653 shares from the basic weighted-average number of common shares outstanding for the three months ended March 31, 2023 and 2022, 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, contingently issuable shares under the Company's employee stock purchase plan, and common stock warrants. 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):

	March 31,	
	2023	2022
Common stock options	3,373,332	1,190,148
Common stock warrants	—	5,883,500
Unvested common stock	2,117,453	2,327,871
ESPP shares	20,002	—
Total potentially dilutive shares	5,510,787	9,401,519

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected to avail itself of this exemption from new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recently Adopted Accounting Standards

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

Recently Issued Accounting Pronouncements

The Company assesses the adoption impacts of recently issued accounting standards by the Financial Accounting Standards Board or other standard setting bodies on the Company's condensed consolidated financial statements as well as material updates to previous assessments, if any. Although there were several other new accounting pronouncements issued or proposed by the FASB, the Company does not believe any of those accounting pronouncements have had or will have a material impact on its financial position or operating results.

3. Other Balance Sheet Details

Property and Equipment

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

	March 31, 2023	December 31, 2022
Furniture and equipment	$ 10	$ 11
Leasehold improvements	378	378
Construction in progress	10,063	5,198
Total property and equipment, at cost	10,451	5,587
Less accumulated depreciation	1	1
Property and equipment, net	$ 10,450	$ 5,586

Depreciation expense for the three months ended March 31, 2023 and 2022 was not material.

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Accrued external research and development costs	$ 11,638	$ 3,510
Accrued payroll and payroll-related costs	1,657	4,018
Other	4,117	682
Total accrued expenses	$ 17,412	$ 8,210

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):

	March 31, 2023	December 31, 2022
Cash and cash equivalents	$ 260,542	$ 279,401
Restricted cash	1,631	1,631
Total cash, cash equivalents and restricted cash	$ 262,173	$ 281,032

4. 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 (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 up to $6.3 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 $6.3 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 March 31, 2023, the Company recorded increases of $1.9 million to the operating lease liability as and when such leasehold improvements were paid for by the landlord. The Company expects to receive all tenant improvement reimbursements during the year ending December 31, 2023. 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 following table summarizes operating lease expense for the three months ended March 31, 2023 (in thousands):

	Three Months Ended March 31, 2023
Lease expense:	
Operating lease expense	$ 779

The Company incurred an immaterial amount of expense related to short-term leases and variable lease costs during the three months ended March 31, 2023. Operating lease expense was not material for the three months ended March 31, 2022.

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

	Three Months Ended March 31,	
	2023	2022
Other information:		
Weighted-average remaining lease term	9.70	4.50
Weighted-average discount rate	7.4%	6.0%

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):

	March 31, 2023
Cash paid for amounts included in the measurement of operating lease liabilities (operating cash flows)	$ 871

At March 31, 2023, the future minimum noncancelable operating lease payments were as follows (in thousands):

	March 31, 2023
Years ending December 31:	
2023	$ 2,613
2024	3,584
2025	3,688
2026	3,784
2027	3,860
Thereafter	21,075
Total undiscounted operating lease payments	38,604
Present value adjustment	(11,113)
Tenant improvement reimbursements	(4,476)
Operating lease liability	23,015
Less current portion of operating lease liability	38
Operating lease liability, net of current portion	$ 22,977

5. 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 March 31, 2023, the Company and Frazier reimbursed each other for various goods and services, including personnel related expenses, travel, insurance, facilities and other various overhead and administrative expenses. As of March 31, 2023 and December 31, 2022, the Company had outstanding amounts due to Frazier of $9,000 and $6,000, respectively, related to these shared operating expenses. For the three months ended March 31, 2023 and 2022, the Company incurred $3,000 and $26,000, respectively, of shared operating expenses.

As described in Note 7, the Company borrowed amounts from Frazier in connection with various convertible note financings. For the three months ended March 31, 2022, the Company recognized a $17.1 million change in fair value of convertible promissory notes in connection with convertible promissory notes issued to Frazier. For the three months ended March 31, 2022, the Company recognized $2.1 million of interest expense in connection with convertible promissory notes issued to Frazier. The convertible promissory notes automatically converted into 10,672,138 shares of the Company's common stock immediately prior to the completion of the IPO.

In connection with the Takeda License (as defined and described in Note 6), 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 6) under which the Company is obligated to pay Takeda for certain services, including pass-through costs, related to research and development and regulatory assistance services, oversight and management of ongoing clinical and research studies, and maintenance of third-party vendor contracts. For the three months ended March 31, 2023 and 2022, the Company incurred $0.2 million and $1.4 million, respectively, of research and development expenses for Takeda’s services. As of March 31, 2023 and December 31, 2022, the Company had $0.3 million and $0.3 million, respectively, of accounts payable and accrued expenses due to Takeda. See Note 6 for further information regarding the Company’s related party transactions with Takeda.

6. Commitments and Contingencies

License Agreement

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 will be responsible, at its own cost, for the development, manufacture and commercialization of HIL-214 products in the Territory, and the Company will integrate certain Japan development activities into its development activities at its own cost. The Company is obligated to use commercially reasonable efforts to develop and commercialize HIL-214 products in the Territory, and to seek regulatory approval for such products throughout the world.

In consideration of the Takeda License, the Company (i) paid Takeda $2.5 million in cash, (ii) issued Takeda 840,500 shares of its common stock at a fair value of $4.4 million, (iii) issued Takeda a warrant (the “Takeda Warrant”) to purchase 5,883,500 shares of its common stock at an exercise price of $0.0000595 per share, which was fully exercised in November 2022, and (iv) issued Takeda a warrant right (the “Takeda Warrant Right”) to receive an additional common stock warrant should Takeda’s fully-diluted ownership of the Company, including the Takeda Warrant, represent less than a certain specified percentage of the fully-diluted capitalization, including shares issuable upon conversion of outstanding convertible promissory notes, calculated immediately prior to the earlier of the closing of the Company’s IPO or a change of control transaction, at an initial fair value of $34,000. In addition, the Company is obligated to pay Takeda an aggregate of $2.5 million upon the release of certain drug product and the completion of certain regulatory activities, which payment was made in March 2022, $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 March 31, 2023, 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 acquisition of the Takeda License has been accounted for as an asset acquisition as substantially all of the fair value is concentrated in a group of similar assets. In March 2022, the Company paid Takeda an aggregate $2.5 million contingent payment upon the release of certain drug products and the completion of certain regulatory activities, which have no alternative future use, and was recorded as in-process research and development in the Company’s condensed consolidated statement of operations for the three months ended March 31, 2022. The Company did not make any milestone payments to Takeda during the three months ended March 31, 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.

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. Beginning November 2022, the Company made 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 $0.2 million during the three months ended March 31, 2023. The Company did not make any matching contributions during the three months ended March 31, 2022.

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.

7. Convertible Promissory Notes and Long-Term Debt

Frazier Convertible Note Financings

During 2019, 2020 and 2021, the Company issued the Frazier Notes for an aggregate of $8.5 million bearing interest at per annum rates ranging from 0.12% to 2.52%. An aggregate of $0.9 million of the Frazier Notes were issued in April, May and September of 2019 (the "2019 Frazier Notes"), an aggregate of $1.3 million of the Frazier Notes were issued in March, August and October of 2020 (the "2020 Frazier Notes") and an aggregate of $6.3 million of Frazier Notes were issued from April to July 2021 (the "2021 Frazier Notes"). The Frazier Notes were generally scheduled to mature 12 to 18 months from the date of issuance. The Company recorded changes in the fair value of the Frazier Notes in the condensed consolidated statements of operations. The Frazier Notes were exchanged for convertible promissory notes newly issued in connection with the August 2021 convertible note financing described below.

August 2021 Convertible Note Financing

On August 31, 2021, the Company entered into a note purchase agreement under which it issued the August 2021 Notes for an aggregate of $139.52 million. Of the August 2021 Notes, $103.75 million were issued to new investors, $25.0 million were issued to Frazier for cash and $10.77 million were issued to Frazier in exchange for the then outstanding principal and accrued interest on the Frazier Notes. The August 2021 Notes carried interest at a rate of 6% per annum, compounded annually. As of March 31, 2022, the outstanding principal balance of the August 2021 Notes was $139.5 million. The principal and accrued interest on the August 2021 Notes automatically converted into 10,672,138 shares of the Company's common stock immediately prior to the completion of the IPO. Of these shares, 2,736,234 were issued to Frazier. For the three months ended March 31, 2022, the Company recognized a $17.1 million change in fair value of convertible promissory notes and recognized $2.1 million of interest expense in connection with convertible promissory notes.

Long-Term Debt

The Company's Term Loan consists of the following (in thousands):

	March 31, 2023
Long-term debt	$ 15,000
Accumulated PIK interest	181
Total principal (including PIK interest)	15,181
Unamortized debt discount	(278)
Long-term debt, net of debt discount	$ 14,903

On April 18, 2022, the Company entered into a Loan and Security Agreement ("Loan Agreement") with Hercules Capital, Inc. ("Hercules"), as administrative and collateral agent, and the lenders party thereto, providing for term loans ("Term Loans") of up to $75.0 million in the aggregate. As of March 31, 2023, the Company had borrowed $15.0 million pursuant to the Loan Agreement and has the right to borrow up to an additional $15.0 million through June 30, 2023 (collectively, "Term Loan 1"). The Company also has the right to borrow up to $20.0 million through June 30, 2023 ("Term Loan 2"). In addition, the Company had the right to borrow $25.0 million through March 31, 2024 ("Term Loan 3"), provided that (i) the Company had announced that the planned Phase 2b clinical trial evaluating the safety, immunogenicity, and efficacy of HIL-214 in infants ("HIL-214 Vaccine Trial") will continue without material adverse modification after completion of the planned interim safety and immunogenicity analysis on the first 200 evaluable subjects in the HIL-214 Vaccine Trial, and (ii) the Company had announced the completion of subject enrollment for the HIL-214 Vaccine Trial, which involved the enrollment of more than 3,000 subjects. However, the Company did not announce the completion of subject enrollment for HIL-214 Vaccine Trial on or prior to March 31, 2023 so Term Loan 3 is not available for draw down. All Term Loans are subject to a minimum draw amount of $5.0 million and no event of default under the Loan Agreement having occurred and is continuing. The borrowings under the Loan Agreement are collateralized by substantially all of the Company's assets, including intellectual property and certain other assets.

The Term Loans bear (a) cash interest at a floating rate of the higher of (i) the Wall Street Journal prime rate (or 5.00% if less) plus 1.05%, or (ii) 4.55% (interest rate of 6.05% as of March 31, 2023), 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, (x) the conditions to Term Loan 3 have been satisfied and (y) the Company has reasonably determined that (i) the HIL-214 Vaccine Trial has achieved the protocol-specified primary efficacy endpoint and (ii) HIL-214 has demonstrated acceptable safety results in the HIL-214 Vaccine Trial, and, as a result, the Company supports the initiation of a Phase 3 registrational trial as the next immediate step in the development of HIL-214, in each case subject to reasonable verification by Hercules, through June 1, 2026. Subsequent to the interest-only period, the Term Loans will be payable in equal monthly installments of principal, plus accrued and unpaid interest, through the maturity date of May 1, 2027. In addition, the Company is obligated to pay a final payment fee equal to the greater of (i) $2.1 million and (ii) 7.15% of the original principal amount of the Term Loans (which is $2.1 million as of March 31, 2023). 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 2.00% of the then outstanding principal balance and the pro rata application of such payment to the final payment fee. After repayment, no Term Loan amounts may be borrowed again.

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

During the three months ended March 31, 2023, the Company has recognized interest expense of $0.4 million related to the Term Loans using the effective interest method. Included in such expense was $0.1 million, related to accretion of the final payment fee to other long-term liabilities, $0.1 million of PIK interest, $0.2 million of coupon interest, and an immaterial amount of debt discount amortization.

Future minimum principal and interest payments, including the final payment fee, as of March 31, 2023 are as follows (in thousands):

	March 31, 2023
Years ending December 31:	
2023	$ 709
2024	$ 967
2025	$ 5,063
2026	$ 7,982
2027	$ 7,405
Total principal payments, interest payments and final payment fee	22,126
Less: interest, PIK interest and final payment fee	(6,945)
Long-term debt	$ 15,181

8. 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.

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 March 31, 2023, 7,127,599 shares were reserved for issuance under the 2022 Plan, of which 4,134,339 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. Stock-based compensation expense related to the ESPP for the three months ended March 31, 2023 was not material.

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, 2022	2,111,989	$ 10.62	9.33	$ 13,330
Granted	1,276,725	17.97		
Exercised	(11,382)	6.99		
Cancelled	(4,000)	6.99		
Balance at March 31, 2023	3,373,332	$ 13.38	9.21	$ 12,973
Vested and expected to vest at March 31, 2023	3,373,332	$ 13.38	9.21	$ 12,973
Exercisable at March 31, 2023	363,259	$ 7.58	8.60	$ 3,255

Stock-Based Compensation Expense

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

	Three Months Ended March 31,	
	2023	2022
Risk-free interest rate	1.9%–4.2%	1.9%–2.5%
Expected volatility	83.4%–94.3%	88.1%–89.5%
Expected term (in years)	5.3–6.1	5.5–6.1
Expected dividend yield	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 March 31,	
	2023	2022
Research and development	$ 1,276	$ 201
General and administrative	1,366	71
Total	$ 2,642	$ 272

The weighted average grant date fair value per share of option grants for the three months ended March 31, 2023 and 2022 was $13.80 and $5.92, respectively. As of March 31, 2023, total unrecognized stock-based compensation cost related to stock options was approximately $29.4 million, which is expected to be recognized over a remaining weighted-average period of approximately 3.2 years.

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

	Number of Unvested Shares
Balance at December 31, 2022	1,584,709
Shares granted	759,266
Shares forfeited	(51,954)
Share vested	(174,568)
Balance at March 31, 2023	2,117,453

The Company issued shares of restricted common stock during the three months ended March 31, 2023, which consisted only of restricted stock units. The Company did not issue any shares of restricted common stock during the three months ended March 31, 2022. The weighted average grant date fair value per share of restricted common stock grants for the three months ended March 31, 2023 was $18.00. As of March 31, 2023, total unrecognized stock-based compensation cost related to restricted stock was approximately $13.1 million, which is expected to be recognized over a remaining weighted-average period of approximately 3.8 years. For accounting purposes, unvested shares of restricted common stock are not considered outstanding until they vest. As of March 31, 2023 and December 31, 2022, 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:

	March 31, 2023
Common stock options outstanding	3,373,332
Shares available for issuance under the Plans	4,134,339
Shares available for issuance under the ESPP	774,574
	8,282,245

9. Subsequent Event

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.

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, 2022 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, 2022 filed with the Securities and Exchange Commission (SEC) on March 17, 2023 (the 2022 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. We expect to report top-line safety and clinical efficacy data in the first quarter of 2024. We believe HIL-214 has the potential to be the first ever vaccine approved for norovirus-related illness and will help grow HilleVax into a leading global vaccines company.

We commenced our operations in 2019 and have devoted substantially all of our resources to date to organizing and staffing our company, business planning, raising capital, in-licensing intellectual property related to our initial vaccine candidate, HIL-214, preparing for 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 and the sale of common stock in our initial public offering (IPO) which closed in May 2022. As of March 31, 2023, we had cash and cash equivalents of $260.5 million. From inception to March 31, 2023, we raised aggregate gross proceeds of $137.2 million from the issuance of convertible promissory notes and, on May 3,

2022, we completed our IPO, whereby we sold 13,529,750 shares of common stock at a public offering price of $17.00 per share, for net proceeds of approximately $209.5 million, after deducting underwriting discounts, commissions and offering costs of approximately $20.5 million.

We do not have any products approved for sale, have not generated any revenue and have incurred net losses since our inception. Our net losses for the three months ended March 31, 2023 and 2022 were $26.9 million and $67.9 million, respectively. As of March 31, 2023, we had an accumulated deficit of $291.9 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical development activities, other research and development activities and pre-commercialization activities. We expect our expenses and operating losses will increase substantially as we advance HIL-214 through clinical trials, seek regulatory approval for HIL-214, expand our clinical, regulatory, quality, manufacturing and commercialization capabilities, incur significant commercialization expenses for marketing, sales, manufacturing and distribution in anticipation of obtaining potential marketing approval for HIL-214, obtain, maintain, protect and enforce our intellectual property, expand our general and administrative support functions, including hiring additional personnel.

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

Financial Operations Overview

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

License Agreement with Takeda

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

We paid Takeda upfront consideration consisting of 840,500 shares of our common stock and a warrant to purchase 5,883,500 shares of our common stock (the Takeda Warrant). We further agreed that, in the event that Takeda's fully-diluted ownership, including the Takeda Warrant, represents less than a certain specified percentage of our fully-diluted capitalization, including shares issuable upon conversion of outstanding convertible promissory notes, calculated immediately prior to the closing of our IPO, we 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 months ended March 31, 2023 and 2022, we incurred $0.2 million and $1.4 million, respectively, of research and development expenses for Takeda's services.

Components of Results of Operations

Operating Expenses

Research and Development

During 2023 and 2022, our research and development expenses have been related to the development of HIL-214. Research and development expenses are recognized as incurred, and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Research and development expenses include:

- salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in research and development efforts;
- external research and development expenses incurred under agreements with CROs and consultants to conduct and support our planned clinical trials of HIL-214; and
- costs related to manufacturing HIL-214 for our planned clinical trials.

We plan to substantially increase our research and development expenses for the foreseeable future as we continue the development of HIL-214. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of HIL-214 or any future vaccine candidates due to the inherently unpredictable nature of clinical and preclinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast whether HIL-214 or any future vaccine candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

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

- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects;
- the number of subjects that participate in the trials;
- the number of doses evaluated in the trials;
- the costs and timing of manufacturing HIL-214 and placebo for use in our trials;

- the drop-out or discontinuation rates of clinical trial subjects;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the phase of development of the vaccine candidate;
- the impact of any interruptions to our operations or to those of the third parties with whom we work due to COVID-19 or other disease outbreaks; and
- the safety, purity, potency, immunogenicity and efficacy of the vaccine candidate.

In-Process Research and Development

In-process research and development expenses for the three months ended March 31, 2022 relate to the Takeda License, and include an aggregate $2.5 million contingent payment upon the release of certain drug products and the completion of certain regulatory activities, which have no alternative future use. We did not incur any in-process research and development expenses during the three months ended March 31, 2023.

General and Administrative

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

Interest Income

Interest income consists of interest on money market funds.

Interest Expense

Interest expense consists of interest on our then outstanding convertible promissory notes and our term loan facility.

Change in Fair Value of Warrant Liabilities

In connection with the Takeda License, we issued the Takeda Warrant and Takeda Warrant Right (together, the Takeda Warrants). The Takeda Warrants were accounted for as liabilities until they met all the conditions for equity classification due to (i) insufficient authorized shares for the Takeda Warrant and (ii) the Takeda Warrant Right is not indexed to our own stock. Prior to our IPO, we adjusted the carrying value of the Takeda Warrants to their estimated fair value at each reporting date, with any change in fair value of the warrant liabilities recorded as an increase or decrease to change in fair value of warrant liabilities in the condensed consolidated statements of operations. The Takeda Warrant, which became exercisable upon our IPO, was for the purchase of 5,883,500 shares of our common stock at an exercise price of $0.0000595 per share and was fully exercised in November 2022. As a result of increasing our authorized shares of common stock in the second quarter of 2022, the Takeda Warrant met the requirements to be equity classified, and we reclassified the fair value of the Takeda Warrant to stockholders' equity. The Takeda Warrant Right expired upon the closing of our IPO without effect to the financial statements since no fair value was allocated to it at that time. Prior to the reclassification to stockholders' equity, the fair value of the Takeda Warrants was derived from the model used to estimate the fair value of our common stock and, upon reclassification, the fair value was based on our IPO price.

Change in Fair Value of Convertible Promissory Notes

We issued convertible promissory notes in 2019, 2020 and 2021 for which we elected the fair value option. We adjusted the carrying value of our convertible promissory notes to their estimated fair value at each reporting date, with any change in fair value of the convertible promissory notes recorded as an increase or decrease to change in fair value of convertible

promissory notes in our condensed consolidated statements of operations. All outstanding convertible promissory notes and related accrued interest converted into shares of our common stock immediately prior to the closing of our IPO.

Prior to our IPO, the fair value of our convertible promissory notes was estimated using a scenario-based analysis that estimated the fair value of the convertible promissory notes based on the probability-weighted present value of expected future investment returns, considering possible outcomes available to the noteholders, including various IPO, settlement, equity financing, corporate transactions and dissolution scenarios. The conversion date fair value of the convertible promissory notes was reclassified to stockholders' equity using our publicly traded closing price on the date the convertible promissory notes were converted to common stock.

Results of Operations

Comparison of the three months ended March 31, 2023 and 2022

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

	Three Months Ended March 31,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 23,164	$ 6,211	$ 16,953
In-process research and development	—	2,500	(2,500)
General and administrative	5,795	2,603	3,192
Total operating expenses	28,959	11,314	17,645
Loss from operations	(28,959)	(11,314)	(17,645)
Other income (expense):			
Interest income	$ 2,574	6	2,568
Interest expense	(449)	(2,064)	1,615
Change in fair value of convertible promissory notes	—	(17,073)	17,073
Change in fair value of warrant liabilities	—	(37,424)	37,424
Other income (expense)	(55)	(18)	(37)
Total other income (expense)	2,070	(56,573)	58,643
Net loss	$ (26,889)	$ (67,887)	$ 40,998

Research and development expenses. Research and development expenses were $23.2 million and $6.2 million for the three months ended March 31, 2023 and 2022, respectively. The increase of $17.0 million primarily consisted of $12.3 million of clinical development expenses for HIL-214, $3.5 million of personnel-related expenses, primarily due to the increase in headcount, including $1.3 million of stock-based compensation expense, and $1.1 million of facility and other expenses.

In-process research and development expenses. We had $2.5 million of in-process research and development expenses for the three months ended March 31, 2022 related to the Takeda License, which was entered into in 2021. We did not incur any in-process research and development expenses for the three months ended March 31, 2023.

General and administrative expenses. General and administrative expenses were $5.8 million and $2.6 million for the three months ended March 31, 2023 and 2022, respectively. The increase of $3.2 million primarily consisted of $1.8 million of personnel-related expenses, primarily due to the increase in headcount, including $1.4 million of stock-based compensation expense, $0.7 million in professional services expenses, primarily due to D&O insurance and clinical trial insurance as well as accounting, audit, tax, valuation and other services incurred as we began operating as a public company, and $0.7 million of facility and other expenses.

Other income (expense). Other income of $2.1 million for the three months ended March 31, 2023 primarily consisted of $2.6 million of interest income on our cash and cash equivalents, partially offset by $0.4 million of interest expense on our term loan facility and $0.1 million of other expenses. Other expense of $56.6 million for the three months ended March 31, 2022 primarily consisted of $2.1 million of interest expense on our outstanding convertible promissory notes, $17.1 million of other expense related to the increase in fair value of our convertible promissory notes and $37.4 million of other expense related to the increase in fair value of the Takeda Warrant.

Liquidity and Capital Resources

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future as we continue the development and potential commercialization of HIL-214, 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 and borrowings under our term loan facility. As of March 31, 2023, we had cash and cash equivalents of $260.5 million.

Term Loan Facility

On April 18, 2022, we entered into a Loan and Security Agreement (Loan Agreement) with Hercules Capital, Inc. (Hercules), as administrative and collateral agent, and the lenders party thereto, providing for term loans (Term Loans) of up to $75.0 million in the aggregate. As of March 31, 2023, our borrowings consisted of $15.0 million and we have the right to borrow up to an additional $15.0 million through June 30, 2023 (collectively, Term Loan 1). We also have the right to borrow up to $20.0 million through June 30, 2023 (Term Loan 2). In addition, we had the right to borrow up to $25.0 million through March 31, 2024 (Term Loan 3), provided that (i) we had announced that our planned Phase 2b clinical trial evaluating the safety, immunogenicity, and efficacy of HIL-214 in infants (HIL-214 Vaccine Trial) will continue without material adverse modification after completion of our planned interim safety and immunogenicity analysis on the first 200 evaluable subjects in the HIL-214 Vaccine Trial and (ii) we had announced the completion of subject enrollment for the HIL-214 Vaccine Trial, which involved the enrollment of more than 3,000 subjects. However, the Company did not announce the completion of subject enrollment for HIL-214 Vaccine Trial on or prior to March 31, 2023 so Term Loan 3 is not available for draw down. All Term Loans are subject to a minimum draw amount of $5.0 million and no event of default having occurred and be continuing. The borrowings under the Loan Agreement are collateralized by substantially all of our assets, including intellectual property and certain other assets.

The Term Loans bear (a) cash interest at a floating rate of the higher of (i) the Wall Street Journal prime rate (or 5.00% if less) plus 1.05%, or (ii) 4.55% (interest rate of 6.05% as of December 31, 2022), 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, (x) the conditions to Term Loan 3 have been satisfied and (y) we have reasonably determined that (i) the HIL-214 Vaccine Trial has achieved the protocol-specified primary efficacy endpoint and (ii) HIL-214 has demonstrated acceptable safety results in the HIL-214 Vaccine Trial, and, as a result, we support the initiation of a Phase 3 registrational trial as the next immediate step in the development of HIL-214, in each case subject to reasonable verification by Hercules, through June 1, 2026. Subsequent to the interest-only period, the Term Loans will be payable in equal monthly installments of principal, plus accrued and unpaid interest, through the maturity date of May 1, 2027. In addition, we are obligated to pay a final payment fee equal to the greater of (i) $2.1 million and (ii) 7.15% of the original principal amount of the Term Loans. We may elect to prepay all or a portion of the Term Loans prior to maturity, subject to a prepayment fee of up to 2.00% of the then outstanding principal balance and the pro rata application of such payment to the final payment fee. After repayment, no Term Loan amounts may be borrowed again.

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

As of March 31, 2023, the total outstanding borrowings, including PIK interest, under the Loan Agreement were $15.2 million. As of March 31, 2023, future minimum principal, interest and final payment fees due under the Loan Agreement were approximately $22.1 million, with $0.7 million payable for the year ending December 31, 2023. See Item 1 of Part I, “Notes to Condensed Consolidated Financial Statements — Note 7 — Convertible Promissory Notes and Long-Term Debt” of this Quarterly Report.

Convertible Promissory Note Financings

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

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

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. Sales of our common stock made pursuant to the Sales Agreement, if any, will be made under our shelf registration statement on Form S-3 to be filed on May 12, 2023, following such time as the registration statement is declared effective by the SEC.

Funding Requirements

Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements through at least the next 12 months. In particular, we expect that our existing cash and cash equivalents will allow us to complete enrollment and dosing in, and report top-line safety and clinical efficacy data for, our Phase 2b NEST-IN1 study and technical transfer and manufacturing readiness for producing clinical trial supply for a Phase 3 study. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing vaccine candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Our future capital requirements will depend on many factors, including:

- the initiation, type, number, scope, results, costs and timing of, our planned clinical trials of HIL-214 and preclinical studies or clinical trials of other potential vaccine candidates we may choose to pursue in the future, including any modifications to clinical development plans based on feedback that we may receive from regulatory authorities;
- the costs and timing of manufacturing for HIL-214 and placebo to be used in our planned clinical trials, as well as commercial scale manufacturing, if any vaccine candidate is approved;
- the costs, timing and outcome of regulatory meetings and reviews of HIL-214 or any future vaccine candidates;
- any delays and cost increases that may result from COVID-19 or other disease outbreak;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional officers and clinical development and commercial personnel;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the timing and amount of the milestone, royalty or other payments we must make to Takeda and any future licensors;
- the costs and timing of establishing or securing sales and marketing capabilities if HIL-214 or future vaccine candidates are approved;

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

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through equity offerings, the Loan Agreement, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, intellectual property, future revenue streams, research programs or vaccine candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our vaccine candidates even if we would otherwise prefer to develop and market such vaccine candidates ourselves.

Cash Flows

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

	Three Months Ended March 31,	
	2023	**2022**
Net cash provided by (used in):		
Operating activities	$ (15,954)	$ (10,715)
Investing activities	(2,985)	(2,500)
Financing activities	80	(99)
Net decrease in cash, cash equivalents and restricted cash	$ (18,859)	$ (13,314)

Operating Activities

Net cash used in operating activities of $16.0 million for the three months ended March 31, 2023 was primarily due to our net loss of $26.9 million and a net change of $7.7 million in our operating assets and liabilities, partially offset by $3.2 million of noncash charges primarily related to $2.6 million of stock-based compensation, $0.4 million related to the amortization of operating lease right-of-use assets, $0.1 million related to amortization of debt discount and $0.1 million related to issuance of PIK interest debt. The net change in operating assets and liabilities was primarily due to an increase of $1.4 million related to operating lease liabilities due to leasehold improvement reimbursements, $1.9 million in prepaid expenses and other current assets and $4.4 million in accounts payable and accrued expenses in support of the growth in our operating activities.

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

Investing Activities

Net cash used in investing activities of $3.0 million for the three months ended March 31, 2023 was due to purchases of property and equipment.

Net cash used in investing activities of $2.5 million for the three months ended March 31, 2022 was primarily due to the contingent payment we paid under the Takeda License.

Financing Activities

Net cash provided by financing activities of $0.1 million for the three months ended March 31, 2023 was due to proceeds from the exercise of common stock options.

Net cash used in financing activities of $0.1 million for the three months ended March 31, 2022 was primarily due to our payment of costs related to our IPO.

Contractual Obligations and Commitments

As of March 31, 2023, 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 2022 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 March 31, 2023, 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 2022 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 March 31, 2023 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, 2022.

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 March 31, 2023, we estimate that we have used approximately $69.8 million of the proceeds from our IPO for general corporate purposes, including to fund the clinical development of HIL-214.

Issuer Repurchases of Equity Securities.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On May 12, 2023, we entered into an At-the-Market Sales Agreement (Sales Agreement) with Stifel, Nicolaus & Company, Incorporated (the Agent), under which we may, from time to time, 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. We will pay the Agent a commission of up to 3.0% of the gross proceeds of any shares of common stock sold under the Sales Agreement.

We are not obligated to sell, and the Agent is not obligated to buy or sell, any shares of common stock under the Sales Agreement. No assurance can be given that we will sell any shares of common stock under the Sales Agreement, or, if we do, as to the price or amount of shares of common stock that we sell or the dates when such sales will take place.

The foregoing description of the Sales Agreement is not complete and is qualified in its entirety by reference to the Sales Agreement, a copy of which will be filed as Exhibit 1.2 to our Registration Statement on Form S-3 filed on May 12, 2023 with the SEC.

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	
10.1	Amended and Restated Employment Letter Agreement, dated January 6, 2023, by and between Robert Hershberg and the Registrant	10-K	3/17/23	10.6	
10.2	Second Amended and Restated Employment Letter Agreement, dated as of January 6, 2023, by and between Aditya Kohli and the Registrant	10-K	3/17/23	10.7	
10.3	Second Amended and Restated Employment Letter Agreement, dated as of January 6, 2023, by and between David Socks and the Registrant	10-K	3/17/23	10.8	
10.4	Amended and Restated Employment Letter Agreement, dated as of January 6, 2023, by and between Shane Maltbie and the Registrant	10-K	3/17/23	10.9	
10.5	Employment Letter Agreement, dated as of January 6, 2023, by and between Astrid Borkowski and the Registrant	10-K	3/17/23	10.10	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				X

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

SIGNATURES

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

HilleVax, Inc.

Date: May 12, 2023

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

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

Date: May 12, 2023

By: /s/ Shane Maltbie

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

Exhibit 31.1

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

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

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

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

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

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

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

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

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

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

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

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

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

Date: May 12, 2023

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

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

Exhibit 31.2

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

I, 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: May 12, 2023

By: /s/ Shane Maltbie

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of HilleVax, Inc. (the "Company") for the period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert Hershberg, M.D., Ph.D., as Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge, that:

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

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

Date: May 12, 2023

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

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of HilleVax, Inc. (the "Company") for the period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Shane Maltbie, as Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge, that:

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

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

Date: May 12, 2023

By: /s/ Shane Maltbie
Shane Maltbie
Chief Financial Officer
(Principal Financial and Accounting Officer)

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