UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2024

OR

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

For the transition period from _____ to _____

Commission File Number: 001-40703

INVIVYD, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**85-1403134**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1601 Trapelo Road, Suite 178 Waltham, MA	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 819-0080

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	IVVD	The Nasdaq Global 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, a 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 November 1, 2024, the registrant had 119,616,035 shares of common stock, $0.0001 par value per share, outstanding.

Table of Contents

		Page
PART I.	FINANCIAL INFORMATION	1
Item 1.	Financial Statements (Unaudited)	1
	Condensed Consolidated Balance Sheets	1
	Condensed Consolidated Statements of Operations and Comprehensive Loss	2
	Condensed Consolidated Statements of Stockholders' Equity (Deficit)	3
	Condensed Consolidated Statements of Cash Flows	5
	Notes to Unaudited Condensed Consolidated Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	25
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	39
Item 4.	Controls and Procedures	39
PART II.	OTHER INFORMATION	40
Item 1.	Legal Proceedings	40
Item 1A.	Risk Factors	40
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	42
Item 5.	Other Information	42
Item 6.	Exhibits	43
Signatures		44

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

INVIVYD, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(In thousands, except share and per share amounts)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 106,869	$ 200,641
Accounts receivable, net	8,154	—
Inventory, net	27,067	—
Prepaid expenses and other current assets	9,011	24,240
Total current assets	151,101	224,881
Property and equipment, net	1,640	1,896
Operating lease right-of-use assets	1,729	2,229
Other non-current assets	7,452	175
Total assets	$ 161,922	$ 229,181
Liabilities, Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 17,707	$ 7,953
Accrued expenses [(1)]	59,401	40,860
Operating lease liabilities, current	1,414	1,443
Other current liability	20	35
Total current liabilities	78,542	50,291
Operating lease liabilities, non-current	219	722
Other non-current liability	—	700
Total liabilities	78,761	51,713
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Preferred stock (undesignated), $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 119,604,035 shares issued and outstanding at September 30, 2024; 110,160,684 shares issued and outstanding at December 31, 2023	12	11
Additional paid-in capital	966,718	909,539
Accumulated other comprehensive loss	(18)	(13)
Accumulated deficit	(883,551)	(732,069)
Total stockholders' equity	83,161	177,468
Total liabilities, preferred stock and stockholders' equity	$ 161,922	$ 229,181

(1) Includes related-party amounts of $1,349 and $700 as of September 30, 2024 and December 31, 2023, respectively (see Note 15).

The accompanying notes are an integral part of these condensed consolidated financial statements.

INVIVYD, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

(In thousands, except share and per share amounts)

	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Revenue:				
Product revenue, net	$ 9,300	$ —	$ 11,564	$ —
Total revenue	9,300	—	11,564	—
Operating costs and expenses:				
Cost of product revenue[1]	806	—	894	—
Research and development[2]	57,850	25,574	119,344	96,393
Acquired in-process research and development[3]	—	4,600	—	5,575
Selling, general and administrative	12,955	12,886	48,973	34,038
Total operating costs and expenses	71,611	43,060	169,211	136,006
Loss from operations	(62,311)	(43,060)	(157,647)	(136,006)
Other income:				
Other income, net	1,572	3,620	6,165	11,017
Total other income, net	1,572	3,620	6,165	11,017
Net loss	(60,739)	(39,440)	(151,482)	(124,989)
Other comprehensive income (loss)				
Unrealized (loss) gain, net of tax	(6)	20	(5)	270
Comprehensive loss	$ (60,745)	$ (39,420)	$ (151,487)	$ (124,719)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.51)	$ (0.36)	$ (1.28)	$ (1.14)
Weighted-average common shares outstanding, basic and diluted	119,495,284	109,754,812	118,163,599	109,333,684

(1) Includes related-party amounts of $463 for both the three and nine months ended September 30, 2024, and no related-party amounts for both the three and nine months ended September 30, 2023 (see Note 15).

(2) Includes related-party amounts of $1,133 and $3,399 for the three and nine months ended September 30, 2024, respectively, and related-party amounts of $1,448 and $6,666 for the three and nine months ended September 30, 2023, respectively (see Note 15).

(3) Includes no related-party amounts for both the three and nine months ended September 30, 2024, and related-party amounts of $4,600 and $4,975 for the three and nine months ended September 30, 2023, respectively (see Note 15).

The accompanying notes are an integral part of these condensed consolidated financial statements.

INVIVYD, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(UNAUDITED)
(In thousands, except share amounts)

	Common Stock		Treasury Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity (Deficit)
Balances at December 31, 2023	110,160,684	$ 11	—	$ —	$ 909,539	$ (13)	$ (732,069)	$ 177,468
Stock-based compensation expense	—	—	—	—	5,379	—	—	5,379
Issuance of common stock, net of issuance costs	9,000,000	1	—	—	39,056	—	—	39,057
Issuance of common stock under the employee stock purchase plan	60,546	—	—	—	89	—	—	89
Unrealized gain, net of tax	—	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	—	(43,496)	(43,496)
Balances at March 31, 2024	119,221,230	$ 12	—	$ —	$ 954,063	$ (12)	$ (775,565)	$ 178,498
Stock-based compensation expense	—	—	—	—	9,128	—	—	9,128
Exercise of stock options	172,223	—	—	—	188	—	—	188
Issuance of common stock under the employee stock purchase plan	49,182	—	—	—	75	—	—	75
Net loss	—	—	—	—	—	—	(47,247)	(47,247)
Balances at June 30, 2024	119,442,635	$ 12	—	$ —	$ 963,454	$ (12)	$ (822,812)	$ 140,642
Stock-based compensation expense	—	—	—	—	3,140	—	—	3,140
Exercise of stock options	124,078	—	—	—	97	—	—	97
Issuance of common stock under the employee stock purchase plan	37,322	—	—	—	27	—	—	27
Unrealized loss, net of tax	—	—	—	—	—	(6)	—	(6)
Net loss	—	—	—	—	—	—	(60,739)	(60,739)
Balances at September 30, 2024	119,604,035	$ 12	—	$ —	$ 966,718	$ (18)	$ (883,551)	$ 83,161

	Common Stock		Treasury Stock		Additional Paid-in	Accumulated Other Comprehensive Income (Loss)	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital		Deficit	Equity (Deficit)
Balances at December 31, 2022	109,044,046	$ 11	—	$ —	$ 889,657	$ (272)	$ (533,426)	$ 355,970
Vesting of restricted common stock from early-exercised options	—	—	—	—	1	—	—	1
Exercise of stock options	423,203	—	—	—	459	—	—	459
Repurchase of unvested restricted common stock	(206,802)	—	206,802	—	—	—	—	—
Retirement of treasury stock	—	—	(206,802)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	5,400	—	—	5,400
Issuance of common stock under the employee stock purchase plan	55,779	—	—	—	83	—	—	83
Unrealized gain, net of tax	—	—	—	—	—	157	—	157
Net loss	—	—	—	—	—	—	(35,321)	(35,321)
Balances at March 31, 2023	109,316,226	$ 11	—	$ —	$ 895,600	$ (115)	$ (568,747)	$ 326,749
Vesting of restricted common stock from early-exercised options	—	—	—	—	1	—	—	1
Exercise of stock options	255,440	—	—	—	215	—	—	215
Repurchase of unvested restricted common stock	(46,600)	—	46,600	—	—	—	—	—
Retirement of treasury stock	—	—	(46,600)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	4,677	—	—	4,677
Issuance of common stock under the employee stock purchase plan	45,267	—	—	—	56	—	—	56
Unrealized gain, net of tax	—	—	—	—	—	93	—	93
Net loss	—	—	—	—	—	—	(50,228)	(50,228)
Balances at June 30, 2023	109,570,333	$ 11	—	$ —	$ 900,549	$ (22)	$ (618,975)	$ 281,563
Vesting of restricted common stock from early-exercised options	—	—	—	—	—	—	—	—
Exercise of stock options	230,291	—	—	—	35	—	—	35
Repurchase of unvested restricted common stock	—	—	—	—	—	—	—	—
Retirement of treasury stock	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	4,264	—	—	4,264
Issuance of common stock under the employee stock purchase plan	45,705	—	—	—	57	—	—	57
Unrealized gain, net of tax	—	—	—	—	—	20	—	20
Net loss	—	—	—	—	—	—	(39,440)	(39,440)
Balances at September 30, 2023	109,846,329	$ 11	—	$ —	$ 904,905	$ (2)	$ (658,415)	$ 246,499

The accompanying notes are an integral part of these condensed consolidated financial statements.

INVIVYD, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(In thousands)

	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Cash flows from operating activities:		
Net loss	$ (151,482)	$ (124,989)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	16,731	14,341
Net amortization of premiums and accretion of discounts on marketable securities	—	(6,256)
Amortization of operating lease right-of-use assets	1,215	1,152
Depreciation expense	382	360
Changes in operating assets and liabilities:		
Accounts receivable	(8,154)	—
Inventory	(23,391)	—
Prepaid expenses and other current assets	15,311	(292)
Other non-current assets	(7,277)	4
Accounts payable	9,714	7,685
Accrued expenses	16,032	(5,452)
Operating lease liabilities	(1,247)	(1,159)
Other current liabilities	(15)	(18)
Other non-current liabilities	(700)	700
Net cash used in operating activities	(132,881)	(113,924)
Cash flows from investing activities:		
Purchases of marketable securities	—	(91,202)
Maturities of marketable securities	—	294,583
Purchases of property and equipment	(145)	(615)
Net cash (used in) provided by investing activities	(145)	202,766
Cash flows from financing activities:		
Proceeds from exercises of stock options	285	709
Proceeds from issuance of common stock under the employee stock purchase plan	191	196
Proceeds from issuance of common stock, net of issuance costs	39,285	—
Payments for offering costs	(507)	—
Payments for repurchases of unvested restricted common stock	—	(1)
Net cash provided by financing activities	39,254	904
Net (decrease) increase in cash and cash equivalents	(93,772)	89,746
Cash and cash equivalents at beginning of period	200,641	92,076
Cash and cash equivalents at end of period	$ 106,869	$ 181,822
Supplemental disclosure of cash flow information		
Deferred offering costs in accrued expense	$ 35	$ —
Deferred offering costs in accounts payable	$ 40	$ —

The accompanying notes are an integral part of these condensed consolidated financial statements.

INVIVYD, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. Nature of the Business and Basis of Presentation

Invivyd, Inc. (together with its consolidated subsidiaries, the "Company") is a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2. The Company's proprietary INVYMAB™ platform approach combines state-of-the-art viral surveillance and predictive modeling with advanced antibody engineering. INVYMAB is designed to facilitate the rapid, serial generation of new monoclonal antibodies ("mAbs") to address evolving viral threats.

On March 22, 2024, the Company received emergency use authorization ("EUA") from the U.S. Food and Drug Administration ("FDA") for PEMGARDA™ (pemivibart) injection, for intravenous use, a half-life extended investigational mAb, for the pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. Recipients should not be currently infected with or have had a known recent exposure to an individual infected with SARS-CoV-2.

In July 2024, the Company submitted a request to the FDA to amend the EUA for PEMGARDA, for the treatment of mild-to-moderate symptomatic COVID-19 in certain immunocompromised patients. The submission utilizes a rapid immunobridging pathway previously aligned in principle with the FDA. The EUA amendment request is based on positive immunobridging analyses of pemivibart versus comparator mAbs and data from the Company's ongoing CANOPY Phase 3 clinical trial in participants with moderate-to-severe immune compromise. The COVID-19 treatment EUA request focuses on the critical treatment needs of people in the U.S. who have moderate-to-severe immune compromise and for whom alternative COVID-19 treatment options are not clinically appropriate or accessible.

PEMGARDA is the Company's first mAb in a planned series of innovative mAb candidates designed to keep pace with SARS-CoV-2 viral evolution. As the SARS-CoV-2 virus evolves over time, the Company anticipates leveraging its INVYMAB platform approach to periodically introduce new or engineered mAb candidates, an approach that would be analogous to the periodic updates made to influenza and COVID-19 vaccines. In January 2024, the Company nominated VYD2311, a next generation mAb candidate for COVID-19, as a drug candidate, and in September 2024, the Company announced dosing of the first participants in a Phase 1 clinical trial of VYD2311. VYD2311 is a mAb with high in vitro neutralization potency shown against prominent SARS-CoV-2 variants tested to date. The Phase 1 randomized, blinded, placebo-controlled clinical trial will evaluate escalating dosing as well as safety, tolerability, pharmacokinetics and immunogenicity of VYD2311 in healthy trial participants. The Phase 1 clinical trial is being conducted in Australia and will evaluate multiple dose levels of VYD2311 through various routes of administration, including exploration of intramuscular administration and subcutaneous administration, which are designed to be more system- and patient-friendly than intravenous administration. The Company expects preliminary data readouts from the Phase 1 clinical trial late in the fourth quarter of 2024 and anticipates additional clinical readouts from the VYD2311 program throughout 2025. Like pemivibart, VYD2311 was engineered from adintrevimab, the Company's investigational mAb that has a robust safety data package and demonstrated clinically meaningful results in global Phase 2/3 clinical trials for both the prevention and treatment of COVID-19.

In May 2024, the Company announced general alignment with the FDA on an expedient, repeatable immunobridging pathway to future potential EUAs for serial, novel mAbs for the prevention and treatment of symptomatic COVID-19. This pathway provides the Company with the opportunity to rapidly, efficiently, and durably deliver high value medicines that prevent and treat symptomatic COVID-19 in vulnerable populations. In addition to developing candidates for COVID-19, the Company expects to apply its INVYMAB platform approach to produce lead molecules for other viral diseases, such as influenza.

The Company was incorporated in the State of Delaware in June 2020. The Company operates as a hybrid company with employees working at its corporate headquarters in Waltham, Massachusetts and remotely. In June 2022, and subsequently amended in September 2022 and August 2024, the Company entered into a lease for dedicated laboratory and office space in Newton, Massachusetts for research and development purposes. In 2022, the Company expanded its research team to enable internal discovery and development of its mAb candidates, while continuing to leverage the Company's existing partnership with Adimab, LLC ("Adimab"). The Company is focused on antibody discovery and use of Adimab's platform technology while building its own internal capabilities. In addition, the Company performs research and development activities internally and engages third parties, including Adimab, to perform ongoing research and development and other services on its behalf.

The Company is subject to a number of risks and uncertainties common to companies in the biopharmaceutical industry, including, but not limited to, completing clinical trials, the ability to raise additional capital to fund operations, obtaining regulatory authorization or approval for product candidates, risks associated with market acceptance and commercialization of products, competition from other products, protection of proprietary intellectual property, compliance with government regulations, dependence on key personnel, the ability to attract and retain qualified employees, and reliance on third-party organizations for the discovery, manufacturing, clinical and commercial success of its product candidates.

To date, the Company has received regulatory authorization for only one product candidate, PEMGARDA, which has not been approved, but has been authorized for emergency use by the FDA under an EUA, for pre-exposure prophylaxis of COVID-19 in certain adults and adolescent individuals (12 years of age and older weighing at least 40 kg). Beyond VYD222 (pemivibart) and VYD2311, all of the Company's other product candidates, other than adintrevimab, are currently in research development. The Company's additional product candidates require significant additional research and development efforts, including extensive clinical testing, and regulatory authorization or approval prior to potential commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and compliance-reporting capabilities. It is uncertain when, if ever, the Company will generate substantial revenue from product sales to be able to fund its operating expenses and capital requirements.

Substantial Doubt about Ability to Continue as a Going Concern

The accompanying condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets, and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has primarily funded its operations with proceeds from sales of convertible preferred stock, proceeds from the Company's initial public offering ("IPO") and net proceeds received from shares of common stock sold under the Sales Agreement (as defined below). In February 2024, the Company sold 9,000,000 shares of its common stock under the Sales Agreement at an average price of $4.50 per share for $39.3 million in net proceeds. After receiving EUA in March 2024, the Company has also funded its operations from sales of PEMGARDA.

The Company has incurred losses and negative cash flows from operations since its inception, including a net loss of $151.5 million for the nine months ended September 30, 2024. As of September 30, 2024, the Company had an accumulated deficit of $883.6 million. The Company may continue to generate operating losses for the foreseeable future.

Based on current operating plans and excluding any contribution from future revenues or external financing, the Company will not have sufficient cash and cash equivalents to fund its operating expenses and capital requirements beyond one year from the issuance of these condensed consolidated financial statements, and therefore, the Company has concluded that there is substantial doubt about its ability to continue as a going concern.

The Company will require additional funding through a combination of contribution from revenues, equity offerings, government or private-party grants, debt financings or other capital sources, such as collaborations with other companies, strategic alliances or licensing arrangements to finance its future operations. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or rights of the Company's stockholders.

If the Company is unable to obtain sufficient capital, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all. The accompanying condensed consolidated financial statements do not include any adjustments related to the recoverability and classification of assets or the amounts and classification of liabilities or any other adjustments that might be necessary should the Company be unable to continue as a going concern.

Basis of Presentation

The Company's condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying condensed consolidated financial statements include the accounts of Invivyd, Inc. and its wholly owned subsidiaries, Invivyd Security Corporation, Invivyd Switzerland GmbH, and Invivyd Netherlands B.V. All intercompany accounts and transactions have been eliminated in consolidation. The Company views its operations and manages its business in one operating segment, which is the business of discovering, developing and commercializing differentiated products for the prevention and treatment of infectious diseases.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of September 30, 2024, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2024 and 2023, the condensed consolidated statements of cash flows for the three and nine months ended September 30, 2024 and 2023 and the condensed consolidated statements of stockholders' equity (deficit) for the three and nine months ended September 30, 2024 and 2023 are unaudited.

The accompanying unaudited condensed consolidated financial statements as of September 30, 2024 and for the three and nine months ended September 30, 2024 and 2023, have been prepared by the Company pursuant to the rules and regulations of the SEC for interim financial statements. The accompanying condensed consolidated balance sheet as of December 31, 2023 was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. Certain information and footnote disclosures

normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. These interim condensed consolidated financial statements should be read in conjunction with the Company's audited annual consolidated financial statements, and the notes thereto, as of and for the year ended December 31, 2023, which are included in the 2023 Form 10-K.

In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's condensed consolidated financial position as of September 30, 2024 and December 31, 2023, the condensed consolidated results of operations for the three and nine months ended September 30, 2024 and 2023, the condensed consolidated cash flows for the three and nine months ended September 30, 2024 and 2023, and changes in stockholders' equity (deficit) for the three and nine months ended September 30, 2024 and 2023 have been made. The Company's condensed consolidated results of operations for the three and nine months ended September 30, 2024 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2024.

2. Summary of Significant Accounting Policies

As of September 30, 2024, the Company's significant accounting policies and estimates, which are detailed in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the U.S. Securities and Exchange Commission ("SEC") on March 28, 2024 (the "2023 Form 10-K") have not changed, except as discussed below.

Inventory

Prior to receiving regulatory approval or authorization, costs related to the manufacturing of inventory are recorded as research and development expense on the Company's consolidated statements of operations and comprehensive loss in the period incurred. In connection with the EUA for PEMGARDA in March 2024, the Company subsequently began capitalizing PEMGARDA inventory costs as it was determined that inventory costs incurred subsequent to the EUA had a probable future economic benefit.

Inventory is stated at the lower of cost or estimated net realizable value with cost determined on a first-in, first-out basis. Inventory costs include raw materials, third-party contract manufacturing, third-party packaging services, freight and overhead. The Company reduces its inventory to net realizable value for potentially excess, dated or obsolete inventory based on a quarterly assessment of the recoverability of its capitalized inventory. The Company periodically reviews inventory levels to identify what may expire prior to expected sale or has a cost basis in excess of its estimated realizable value and writes-down such inventories as appropriate as a component of costs of goods sold in the consolidated statements of operations and comprehensive loss.

Concentrations of Credit Risk, Significant Suppliers and License Rights

Financial instruments that potentially expose the Company to concentrations of credit risk consist of cash, cash equivalents and accounts receivable.

As of September 30, 2024, the Company invested its excess cash in money market funds that are subject to minimal credit and market risks. The Company maintains its existing cash and cash equivalents at three accredited financial institutions. From time to time, these deposits may exceed federally insured limits. The Company has not experienced any losses historically in these accounts. Accordingly, the Company does not believe it is exposed to unusual credit risk related to its existing cash and cash equivalents beyond the normal credit risk associated with commercial banking relationships.

As of September 30, 2024, the Company's net product revenue was generated from sales to the Title Company (as defined below) and three third-party specialty distributors (see "Revenue Recognition" for additional information).

The Company is dependent on third-party organizations to manufacture and process its product candidates for its research and development programs. In particular, the Company relies on a single third-party contract manufacturer to produce and process its product candidates and to manufacture supply of its product candidates for preclinical and clinical activities. The Company also currently relies on this same third-party contract manufacturer for any anticipated requirements of commercial supply, including both drug substance and drug product (see Note 9). The Company expects to continue to be dependent on a small number of third-party organizations to supply it with its requirements for all product candidates. The Company's research and development programs, including any associated commercialization efforts, could be adversely affected by a significant interruption in the supply of the necessary materials.

The Company is dependent on a limited number of third parties that provide license rights used by the Company in the development and commercialization of its product candidates and programs. Through September 30, 2024, the Company's research and development programs primarily relate to rights conveyed by Adimab (see Note 7). The Company could experience delays in the development and commercialization of its product candidates and programs if the Adimab agreements or any other license agreement utilized in the Company's research and development activities is terminated, if the Company fails to meet the obligations required under its arrangements, or if the Company is unable to successfully secure new strategic alliances or licensing agreements.

Accounts Receivable

Accounts receivable as of September 30, 2024 is comprised of $8.2 million of PEMGARDA product sales to the Title Company (as defined below) and three third-party specialty distributors (see "Revenue Recognition" for additional information).

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606 - Revenue from Contracts with Customers ("ASC 606"). Under ASC 606, an entity recognizes revenue when or as performance obligations are satisfied by transferring control of promised goods or services to the customer, in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services.

To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. At contract inception, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net

Following EUA from the FDA in March 2024, the Company began generating product revenue from sales of PEMGARDA in April 2024.

The Company entered into a third-party logistics distribution agreement (the "3PL Agreement") to engage a logistics distribution agent (the "3PL Agent") to distribute the Company's products to its customers. The 3PL Agent provides services to the Company that include storage, distribution, processing product returns, customer service support, logistics support, electronic data interface and system access support. Revenue is recognized when or as performance obligations are satisfied by transferring control of promised goods to a customer, generally upon delivery, based on an amount that reflects the consideration to which the Company expected to be entitled.

To date, the Company applied for mandatory distribution licenses that some states require for the Company to sell its product throughout the U.S. In order for the Company to execute sales in the U.S. prior to obtaining such licenses, the Company and an affiliate of the 3PL Agent (the "Title Company") entered into a Temporary Title Model Agreement (the "Temporary Title Model Agreement"), which was an amendment to the 3PL Agreement, so that the Title Company could purchase and take title to the product and sell the product to the specialty distributors who contracted to purchase the product from the Company. Although under the Temporary Title Model Agreement, the Title Company took title to the product, the economic substance of the transaction provided that the Title Company did not possess the risk of loss or participate in the significant risks and rewards of ownership of the product or have the ability to control, direct the use of, and obtain substantially all of the remaining benefits from the product. Accordingly, the Company did not recognize revenue upon the transfer of the goods at the time of sale to the Title Company and recognized revenue when the goods were sold from the Title Company to the specialty distributors.

In July 2024, the Company obtained nearly all of the necessary state distribution licenses to sell its products throughout the U.S. and ceased using the Temporary Title Model Agreement process in the third quarter of 2024.

Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances.

Discounts and Allowances

The Company records reserves, based on contractual terms, for the following components of variable consideration related to product sold during the reporting period, as well as its estimate of product that remains in the distribution channel inventory of its customers at the end of the reporting period, if applicable. On a quarterly basis, the Company updates its estimates, if necessary, and records any material adjustments in the period they are identified.

Trade Discounts and Distributor Fees

The Company provides customary discounts on PEMGARDA sales for prompt payment, the terms of which are explicitly stated in its contracts. The Company also pays fees to specialty distributors for sales order management, data, and distribution services, the terms of which are also explicitly stated in its contracts. Such fees are not for a distinct good or service and, accordingly, are recorded as a reduction of revenue, as well as a reduction to accounts receivable (trade discounts) or as a component of accrued expenses (distributor fees).

Government Chargebacks and Rebates

The Company is subject to discount obligations under its contract with the U.S. Department of Veterans Affairs. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability, which is included as a component of accrued expenses.

Product Returns

The Company offers a right of return for purchased units of PEMGARDA for damage, defect, recall, and/or product expiry, provided the product expiry is within a specified period as set forth in the Company's return goods policy. The Company estimates the

amount of product sales that will be returned using quantitative and qualitative considerations. Reserves for estimated returns are recorded as a reduction of product revenue in the period that the related revenue is recognized, as well as a component of accrued expenses.

Other Incentives

Other incentives include a co-pay assistance program for eligible patients with commercial insurance in the U.S. The co-pay assistance program assists certain commercially insured patients by reducing each participating patient's financial responsibility for the purchase price, up to a specified dollar amount of assistance.

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, research and development expenses and related prepaid or accrued costs, stock-based compensation expense, revenue, including discounts and allowances, and inventory obsolescence. The Company bases its estimates on historical experience, known trends and other market-specific or relevant factors it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ materially from those estimates or assumptions.

Recently Issued and Adopted Accounting Pronouncements

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of its IPO. However, if certain events occur prior to the end of such five-year period, including if it becomes a "large accelerated filer," its annual gross revenues exceeds $1.235 billion or it issues more than $1.0 billion of non-convertible debt in the previous three-year period, it will cease to be an emerging growth company prior to the end of such five-year period. For so long as the Company remains an emerging growth company, it is permitted and intends to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. For example, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"). ASU 2023-07 requires disclosure of incremental segment information on an annual and interim basis. The amendments also require companies with a single reportable segment to provide all disclosures required by this amendment and all existing segment disclosures in ASC 280, Segment Reporting. The amendments are effective for fiscal years beginning after December 15, 2023, and interim periods beginning after December 15, 2024. The Company is currently evaluating the potential impacts of ASU 2023-07 on its consolidated financial statement disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"). ASU 2023-09 modifies the rules on income tax disclosures to enhance the transparency and decision-usefulness of income tax disclosures, particularly in the rate reconciliation table and disclosures about income taxes paid. The amendments are intended to address investors' requests for income tax disclosures that provide more information to help them better understand an entity's exposure to potential changes in tax laws and the ensuing risks and opportunities and to assess income tax information that affects cash flow forecasts and capital allocation decisions. The guidance also eliminates certain existing disclosure requirements related to uncertain tax positions and unrecognized deferred tax liabilities. The guidance is effective for the Company for the annual period beginning after December 15, 2024. All entities should apply the guidance prospectively but have the option to apply it retrospectively. The Company is currently evaluating the potential impacts of ASU 2023-09 on its consolidated financial statement disclosures.

3. Fair Value Measurements

Fair Value Measurements

Certain assets of the Company are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents are carried at fair value, determined according to the fair value hierarchy described above. The carrying values of the Company's accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities.

The following tables present the Company's fair value hierarchy for its assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements at September 30, 2024:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 101,553	$ —	$ —	$ 101,553
	$ 101,553	$ —	$ —	$ 101,553

	Fair Value Measurements at December 31, 2023:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 198,193	$ —	$ —	$ 198,193
	$ 198,193	$ —	$ —	$ 198,193

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

There were no changes to the valuation methods during the three and nine months ended September 30, 2024 or 2023.

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers into or out of Level 1, Level 2 or Level 3 fair value measurements during the three and nine months ended September 30, 2024 or 2023.

4. Inventory

The following table presents inventories (in thousands):

	September 30, 2024	December 31, 2023
Work in process	$ 26,216	$ —
Finished goods	851	—
	$ 27,067	$ —

The Company did not have any inventory as of December 31, 2023.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Prepaid external research, development and manufacturing costs	$ 5,744	$ 19,962
Prepaid insurance	205	1,770
Prepaid compensation and other	2,602	1,575
Interest receivable	460	933
	$ 9,011	$ 24,240

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Accrued external research, development and manufacturing costs	$ 49,268	$ 28,151
Accrued professional and consultant fees	2,377	1,732
Accrued employee compensation	3,280	10,752
Accrued inventory	2,760	—
Other	1,716	225
	$ 59,401	$ 40,860

7. License and Collaboration Agreements

Adimab Assignment Agreement

In July 2020, the Company entered into an Assignment and License Agreement with Adimab (the "Adimab Assignment Agreement"). Under the terms of the agreement, Adimab assigned to the Company all rights, title and interest in and to certain of its coronavirus-specific antibodies (each, a "CoV Antibody" and together, the "CoV Antibodies"), including modified or derivative forms thereof, and related intellectual property. In addition, Adimab granted to the Company a non-exclusive, worldwide, royalty-bearing, sublicensable license to certain of its platform patents and technology for the development, manufacture and commercialization of the CoV Antibodies and pharmaceutical products containing or comprising one or more CoV Antibodies (each, a "Product") for all indications and uses, with the exception of certain diagnostic uses and use as a research reagent (the "Field"). The Company is entitled to sublicense the assigned rights and licensed intellectual property solely with respect to any CoV Antibody or Product, subject to specified conditions of the agreement. The Company is obligated to use commercially reasonable efforts to achieve specified development and regulatory milestones for Products in certain major markets and to commercialize a product in any country in which the Company obtains marketing approval.

Pursuant to the terms of the Adimab Assignment Agreement, the parties will establish one or more work plans that set forth the activities to be performed under the agreement (each, a "Work Plan"), and each party is responsible for performing the obligations to which it is assigned under such Work Plans. Upon execution of the Adimab Assignment Agreement, the Company and Adimab agreed on an initial Work Plan that outlined the services that will be performed commencing at inception of the arrangement. The Company is obligated to pay Adimab quarterly for its services performed under each Work Plan at a specified full-time equivalent rate. Otherwise, the Company is solely responsible for the development, manufacture and commercialization of the CoV Antibodies and associated Products at its own cost and expense. The Company is solely responsible for preparing and submitting all investigational new drug applications, new drug applications, biologics license applications and other regulatory filings for the CoV Antibodies and Products in the Field, and for obtaining and maintaining all marketing approvals for Products in the Field, at its sole expense. Additionally, the Company has the sole right to prosecute, maintain, enforce and defend patents covering the CoV Antibodies and Products, all at its own expense.

Amounts paid with respect to services performed by Adimab on the Company's behalf under the Adimab Assignment Agreement are recognized as research and development expense as such amounts are incurred. During the three and nine months ended September 30, 2024 and 2023, the Company did not recognize any research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab Assignment Agreement. Please refer to Note 15 for additional information.

The Company is obligated to pay Adimab up to $16.5 million upon the achievement of specified development and regulatory milestones for the first Product under the agreement that achieves such specified milestones and up to $8.1 million upon the achievement of specified development and regulatory milestones for the second Product under the agreement that achieves such specified milestones. The maximum aggregate amount of milestone payments payable under the agreement for any and all Products is $24.6 million, of which a total of $11.1 million has been achieved and paid as of September 30, 2024; however, milestone payments do not accrue for certain *in vitro* diagnostic devices consisting of or containing CoV Antibodies.

In March 2023, the Company achieved the first specified milestone for the second product candidate under the Adimab Assignment Agreement upon dosing of the first subject in a Phase 1 clinical trial evaluating VYD222, which obligated the Company to make a $0.4 million milestone payment to Adimab, which was paid in May 2023. In September 2023, the Company achieved specified milestones for the second product candidate under the Adimab Assignment Agreement upon dosing of the first subject in a pivotal clinical trial evaluating VYD222, which obligated the Company to make a $3.2 million milestone payment to Adimab, which was paid in October 2023. The next potential milestone under the Adimab Assignment Agreement is a low single-digit million-dollar regulatory milestone, which was not considered probable under U.S. GAAP and therefore, no expense was recognized as of September 30, 2024.

During both the three and nine months ended September 30, 2024, the Company did not recognize any in-process research and development ("IPR&D") expense with respect to contingent consideration payable under the Adimab Assignment Agreement. During the three and nine months ended September 30, 2023, the Company recognized $3.2 and $3.6 million, respectively, of IPR&D expense

with respect to contingent consideration payable under the Adimab Assignment Agreement. Except for milestone payments of $11.1 million incurred through December 31, 2023, no other milestone payments have been paid to or have been earned by Adimab through September 30, 2024.

The Company is obligated to pay Adimab royalties of a mid-single-digit percentage based on net sales of any Products, beginning upon the first commercial sale of a Product in accordance with the Adimab Assignment Agreement. The royalty rate is subject to reductions specified under the agreement. Royalties are due on a Product-by-Product and country-by-country basis beginning upon the first commercial sale of each Product and ending on the later of (i) 12 years after the first commercial sale of such Product in such country and (ii) the expiration of the last valid claim of a patent covering such Product in such country (the "Royalty Term"). During both the three and nine months ended September 30, 2024, the Company expensed $0.5 million of royalties and reserves all rights under the Adimab Assignment Agreement and the applicable law. During both the three and nine months ended September 30, 2023, the Company did not expense any royalties. In addition, the Company is obligated to pay Adimab royalties of a specified percentage in the range of 45% to 55% of any compulsory sublicense consideration received by the Company in lieu of certain royalty payments.

Unless earlier terminated, the Adimab Assignment Agreement remains in effect until the expiration of the last-to-expire Royalty Term for any and all Products. The Company may terminate the agreement at any time for any or no reason upon advance written notice to Adimab, or in the event of a material breach by Adimab that is not cured with specific periods. Adimab may only terminate the agreement for an uncured material breach by the Company for its due diligence obligation or a payment obligation. Upon any termination of the agreement prior to its expiration, all licenses and rights granted pursuant to the arrangement will automatically terminate and revert to the granting party and all other rights and obligations of the parties will terminate.

The Company concluded that the Adimab Assignment Agreement represented an asset acquisition of IPR&D assets with no alternative future use. The arrangement did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in a single asset.

Adimab Collaboration Agreement

In May 2021, the Company entered into a Collaboration Agreement with Adimab, as amended in November 2022 and September 2023 (the "Adimab Collaboration Agreement"), for the discovery and optimization of proprietary antibodies as potential therapeutic product candidates. Under the Adimab Collaboration Agreement, the Company and Adimab could collaborate on research programs for a specified number of targets selected by the Company within a specified time period. Under the Adimab Collaboration Agreement, Adimab granted the Company a worldwide, non-exclusive license to certain of its platform patents and technology and antibody patents to perform the Company's responsibilities during the ongoing research period and for a specified evaluation period thereafter (the "Evaluation Term"). In addition, the Company granted Adimab a license to certain of the Company's patents and intellectual property solely to perform Adimab's responsibilities under the research plans. Under the Adimab Collaboration Agreement, the Company has an exclusive option, on a program-by-program basis, to obtain licenses and assignments to commercialize selected products containing or comprising antibodies directed against the applicable target, which option may be exercised upon the payment of a specified option fee for each program. Upon exercise of an option by the Company, Adimab will assign to the Company all right, title and interest in the antibodies of the optioned research program and will grant the Company a worldwide, royalty-free, fully paid-up, non-exclusive, sublicensable license under the Adimab platform technology for the development, manufacture and commercialization of the antibodies for which the Company has exercised its options and products containing or comprising those antibodies. The Company is obligated to use commercially reasonable efforts to develop, seek marketing approval for, and commercialize one product that contains an antibody discovered in each optioned research program.

The Company agreed to pay Adimab a quarterly fee of $1.3 million, which could be cancelled at the Company's option at any time. For so long as the Company was paying such quarterly fee (or earlier if (i) the Company experienced a change of control after the third anniversary of the Adimab Collaboration Agreement or (ii) Adimab owned less than a specified percentage of the Company's equity), Adimab and its affiliates agreed not to assist or direct certain third parties to discover or optimize antibodies intended to bind to coronaviruses or influenza viruses. Under the Adimab Collaboration Agreement, the Company could also elect to decrease the scope of Adimab's exclusivity obligations and obtain a corresponding decrease in the quarterly fee. In December 2023, the Company elected to decrease the scope of Adimab's exclusivity obligations to cover only coronaviruses and obtained a corresponding decrease in the quarterly fee. Effective January 2024, the Company became obligated to pay Adimab a quarterly fee of $0.6 million. During the three and nine months ended September 30, 2024, the Company recognized $0.6 million and $1.8 million, respectively, of research and development expense related to the quarterly fee. During the three and nine months ended September 30, 2023, the Company recognized $1.3 million and $3.9 million, respectively, of research and development expense related to the quarterly fee.

For each agreed upon research program that is commenced, the Company is obligated to pay Adimab quarterly for its services performed during a given research program at a specified full-time equivalent rate; a discovery delivery fee of $0.2 million; and an optimization completion fee of $0.2 million. For each option exercised by the Company to commercialize a specific research program, the Company is obligated to pay Adimab an exercise fee of $1.0 million. Amounts paid with respect to services performed by Adimab on the Company's behalf in each of the research programs under the Adimab Collaboration Agreement are recognized as research and development expense as such amounts are incurred and services are rendered. During both the three and nine months ended

September 30, 2024, the Company did not recognize any research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab Collaboration Agreement. During the three and nine months ended September 30, 2023, the Company recognized $0.1 million and $0.5 million, respectively, of research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab Collaboration Agreement. During the three and nine months ended September 30, 2024, the Company did not recognize any IPR&D expense related to drug delivery fees, optimization completion fees or option exercise fees. During both the three and nine months ended September 30, 2023, the Company recognized $1.0 million, $0.2 million, and $0.2 million of IPR&D expense related to an option exercise fee, a drug delivery fee and an optimization completion fee, respectively. Please refer to Note 15 for additional information.

The Company is obligated to pay Adimab up to $18.0 million upon the achievement of specified development and regulatory milestones for each product under the Adimab Collaboration Agreement that achieves such milestones. The next potential milestone under the Adimab Collaboration Agreement is a low single-digit million-dollar clinical milestone, which was not considered probable under U.S. GAAP and therefore, no expense was recognized as of September 30, 2024. The Company is also obligated to pay Adimab royalties of a mid-single-digit percentage based on net sales of any product under the Adimab Collaboration Agreement, subject to reductions for third-party licenses. The royalty term will expire for each product on a country-by-country basis upon the later of (i) 12 years after the first commercial sale of such product in such country and (ii) the expiration of the last valid claim of any patent claiming composition of matter or method of making or using any antibody identified or optimized under the Adimab Collaboration Agreement in such country.

In addition, the Company is obligated to pay Adimab for Adimab's performance of certain validation work with respect to certain antigens acquired from a third party. In consideration for this work, the Company is obligated to pay Adimab royalties of a low single-digit percentage based on net sales of products that contain such antigens for the same royalty term as antibody-based products, but the Company is not obligated to make any milestone payments for such antigen products. Through September 30, 2024, no royalty payments have been paid to or have been earned by Adimab under the Adimab Collaboration Agreement.

The Adimab Collaboration Agreement will expire (i) if the Company does not exercise any option, upon the conclusion of the last Evaluation Term for the research programs, or (ii) if the Company exercises an option, on the expiration of the last royalty term for a product in a particular country, unless the agreement is earlier terminated. The Company may terminate the Adimab Collaboration Agreement at any time upon advance written notice to Adimab. In addition, subject to certain conditions, either party may terminate the Adimab Collaboration Agreement in the event of a material breach by the other party that is not cured within specified periods.

The Company concluded that the Adimab Collaboration Agreement represented an asset acquisition of IPR&D with no alternative future use. Therefore, payments made by the Company to Adimab for milestones achieved will be recognized as IPR&D expense in the related period in which the services are performed or the related milestone is considered probable of achievement. Amounts paid with respect to services performed by Adimab on the Company's behalf under the Adimab Collaboration Agreement are recognized as research and development expense as such amounts are incurred and services are rendered. Please refer to Note 15 for additional information.

Adimab Platform Transfer Agreement

In September 2022 (the "Adimab Platform Transfer Agreement Effective Date"), the Company entered into a Platform Transfer Agreement with Adimab (the "Adimab Platform Transfer Agreement") under which the Company was granted the right under certain intellectual property of Adimab to practice certain elements of Adimab's platform technology, including B-cell cloning using Adimab's proprietary yeast cell lines and other antibody optimization libraries, trade secrets, protocols and software of Adimab, to discover, engineer and optimize antibodies. The Company does not have access to Adimab's proprietary discovery libraries. The Company was also granted the right under certain intellectual property of Adimab to research, develop, make, sell and exploit such antibodies and products containing such antibodies. The Adimab platform has been transferred to the Company in accordance with the terms of the Adimab Platform Transfer Agreement. In September 2022, the Company recognized $3.0 million as IPR&D expense in connection with the upfront consideration payable for the rights assigned pursuant to the Adimab Platform Transfer Agreement.

The Company is obligated to pay Adimab an annual fee of single digit millions on each of the first four anniversaries of the Adimab Platform Transfer Agreement Effective Date, which allows the Company to receive material improvements to the platform technology, including materially improved antibody optimization libraries, updates that provide new functionality to the platform, and software upgrades, from Adimab through June 2027. The first annual fee became due in September 2023 and was paid in October 2023. During the three and nine months ended September 30, 2024, the Company recognized a portion of the annual fees as research and development expense. Beginning in July 2027 and ending in June 2042, unless terminated earlier, the Company has the option to receive additional material improvements to the platform technology from Adimab, subject to a commercially reasonable fee to be negotiated by the parties.

The Company is obligated to pay Adimab up to $9.5 million upon the achievement of specified development and regulatory milestones for each product under the Adimab Platform Transfer Agreement that achieves such milestones. The next potential milestone under the Adimab Platform Transfer Agreement is a mid-six-digit dollar preclinical milestone, which was not considered probable under U.S. GAAP and therefore, no expense was recognized as of September 30, 2024.

In addition, the Company is obligated to pay Adimab royalties of a low single-digit percentage based on net sales of products containing an antibody discovered, engineered or optimized using Adimab's platform technology, subject to reductions specified under the Adimab Platform Transfer Agreement. Royalties are due on a product-by-product and country-by-country basis. The royalty term will expire for each product on a country-by-country basis upon the later of (i) 12 years after the first commercial sale of such product in such country and (ii) the expiration of the last valid claim of a program antibody patent for covering the program antibody contained in such product in such country. Through September 30, 2024, no royalty payments have been paid to or have been earned by Adimab under the Adimab Platform Transfer Agreement.

The Company may terminate the Adimab Platform Transfer Agreement at any time upon advance written notice to Adimab. In addition, subject to certain conditions, either party may terminate the Adimab Platform Transfer Agreement in the event of a material breach by the other party that is not cured within specified periods or in connection with the other party's insolvency.

The Company concluded that the Adimab Platform Transfer Agreement represented an asset acquisition of IPR&D with no alternative future use. Therefore, payments made by the Company to Adimab for milestones achieved will be recognized as IPR&D expense in the related period in which the services are performed or the related milestone is considered probable of achievement. Amounts paid with respect to the annual material improvement fees are recognized as research and development expense as such amounts are incurred. Please refer to Note 15 for additional information.

WuXi Biologics Cell Line License Agreement

In December 2020, as amended in February 2023 and March 2024, the Company entered into a Cell Line License Agreement with WuXi Biologics (Hong Kong) Limited ("WuXi Biologics") (the "Cell Line License Agreement"), under which WuXi Biologics granted to the Company a non-exclusive, non-transferable, worldwide, royalty-bearing, sublicensable license to certain of its intellectual property, including certain patent rights associated with a proprietary cell line developed by WuXi Biologics for the exploitation of certain recombinant antibodies developed using such proprietary cell line (each, a "Licensed Product"). Each Licensed Product generated under the arrangement will be produced from a transformed or transfected version of the proprietary cell line derived by WuXi Biologics (each of such transformed or transfected cell lines, a "Licensed Cell Line").

In December 2020, the Company recognized an upfront fee of $0.2 million upon completion of cell bank generation for the first Licensed Cell Line created under the Cell Line License Agreement.

The Company is also obligated to pay royalties in the range of less than 1.0% to WuXi Biologics based on net sales of any Licensed Products manufactured by the Company or a third party on its behalf. However, if the Company uses WuXi Biologics to manufacture all of its commercial supplies for Licensed Products, no royalties would be owed by the Company to WuXi Biologics for net sales of Licensed Products. The Company has an option to buy out its royalty obligations on a Licensed Cell Line-by-Licensed Cell Line basis by making a one-time payment in the low eight-figures to WuXi Biologics. Royalties are due on a Licensed Product-by-Licensed Product basis commencing on the date of the first commercial sale of the applicable product and continuing for so long as the Company commercializes Licensed Products or, if earlier, until the Company exercises its option to buy out the royalty obligations. Through September 30, 2024, no royalties had become due to WuXi Biologics.

The Cell Line License Agreement remains in effect until it is terminated. The Company may terminate the Cell Line License Agreement at any time with notice to WuXi Biologics. WuXi Biologics may terminate the Cell Line License Agreement in the event the Company fails to make a payment when due under the Cell Line License Agreement and such non-payment is not cured within a specified period after notice. Either party may terminate the Cell Line License Agreement in the event of a material breach by the other party that is not cured within a specified period after notice. Upon termination of the Cell Line License Agreement, the license conveyed by WuXi Biologics to the Company will continue in full force and effect with respect to all Licensed Products manufactured using the Licensed Cell Line already generated under the Cell Line License Agreement, provided that the Company continues to pay its royalty obligations, if any.

The Company concluded that the Cell Line License Agreement represented an asset acquisition of IPR&D with no alternative future use. The Cell Line License Agreement did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in a single asset. The Company did not recognize any IPR&D expense under the Cell Line License Agreement during the three and nine months ended September 30, 2024. The Company recognized $0 and $0.6 million of IPR&D expense under the Cell Line License Agreement during the three and nine months ended September 30, 2023, respectively.

8. Population Health Partners, L.P.

In November 2022 (the "PHP Effective Date"), the Company entered into a Master Services Agreement with Population Health Partners, L.P. ("PHP"), pursuant to which PHP agreed to provide services and create deliverables for the Company as agreed between the Company and PHP and set forth in one or more work orders under such agreement (the "PHP MSA"). The term of the PHP MSA commenced on the PHP Effective Date for an initial term of one year. The PHP MSA renewed for subsequent periods, until terminated in accordance with its terms. The PHP MSA was terminated effective in July 2024. On the PHP Effective Date, the Company and PHP

entered into the first work order under the PHP MSA (the "PHP Work Order"), pursuant to which PHP agreed to advise and counsel the Company regarding clinical development and regulatory matters with respect to the Company's product candidates. The PHP Work Order was effective for six months from the PHP Effective Date and terminated in accordance with its terms in May 2023. The PHP MSA contained customary confidentiality provisions and representations and warranties of the parties, as well as mutual non-solicitation of certain employees during the term of the PHP MSA and for a period of one year thereafter.

As compensation for the services and deliverables under the PHP Work Order, the Company paid PHP a cash fee of $0.5 million per month during the term of the PHP Work Order for an aggregate fee of $3.0 million (the "Aggregate Fee").

During the three and nine months ended September 30, 2024, the Company did not recognize any research and development expense related to the cash compensation paid to PHP. During the three and nine months ended September 30, 2023, the Company recognized $0 and $2.3 million, respectively, of research and development expense related to the cash compensation paid to PHP. Please refer to Note 15 for additional information.

In addition to the cash compensation, on the PHP Effective Date, the Company issued a warrant to purchase shares of the Company's common stock to PHP (the "PHP Warrant"). The exercise price of the PHP Warrant is $3.48 per share of the Company's common stock, which was equal to the Nasdaq official closing price of a share of the Company's common stock on the trading day immediately prior to the PHP Effective Date. The PHP Warrant is exercisable for up to an aggregate of 6,824,712 shares of the Company's common stock, and vests in three separate tranches as follows:

- 3,591,954 shares of the Company's common stock underlying the PHP Warrant vests if the Company's Market Capitalization (as defined below) equals or exceeds $758,517,511 by November 15, 2028;

- 1,795,977 shares of the Company's common stock underlying the PHP Warrant vests if the Company's Market Capitalization equals or exceeds $1,137,776,266 by November 15, 2029; and

- 1,436,781 shares of the Company's common stock underlying the PHP Warrant vests if the Company's Market Capitalization equals or exceeds $1,517,035,022 by November 15, 2030.

For purposes of the PHP Warrant, the term "Market Capitalization" means, with respect to a particular trading day, the total value of the outstanding shares of the Company's common stock on such date, calculated by multiplying the Company's volume weighted-average price for the ten (10) trading days immediately preceding such date by the Company's total number of outstanding shares of the Company's common stock as reflected in (i) the Company's most recent periodic or annual report filed with the SEC (e.g., Annual Report on Form 10-K or Quarterly Report on Form 10-Q), as the case may be, (ii) a more recent public announcement by the Company or (iii) a more recent written notice by the Company or the Company's transfer agent setting forth the number of shares of the Company's common stock outstanding.

The PHP Warrant is exercisable for ten years from the PHP Effective Date with respect to the vested portion(s) of the PHP Warrant. The PHP Warrant may be exercised by cash exercise or, at the election of PHP, by means of "cashless exercise" pursuant to a formula set forth in the PHP Warrant. The Company also granted PHP certain "piggyback" registration rights requiring the Company to register any shares of the Company's common stock underlying the PHP Warrant for resale with the SEC, subject to the Company's existing obligations under that certain Second Amended and Restated Investors' Rights Agreement, dated April 16, 2021, by and among the Company and the investors party thereto, which registration rights PHP exercised in January 2024.

Upon the consummation of a fundamental transaction of the Company (as defined in the PHP Warrant) on or prior to November 15, 2028, all of the shares underlying the PHP Warrant would become immediately vested and exercisable; upon the consummation of a fundamental transaction of the Company after November 15, 2028 but on or prior to November 15, 2029, the shares underlying the second and third tranches of the PHP Warrant would become immediately vested and exercisable; and upon the consummation of a fundamental transaction of the Company after November 15, 2029 but on or prior to November 15, 2030, the shares underlying the third tranche of the PHP Warrant would become immediately vested and exercisable.

Refer to Note 11 for additional information on the PHP Warrant.

Tamsin Berry, a member of the Company's board of directors, is a Limited Partner of PHP.

9. Commitments and Contingencies

Operating Lease Commitments

In September 2021, the Company entered into a five-year noncancelable facilities lease agreement for approximately 9,600 square feet of office space in Waltham, Massachusetts, which provides for monthly rental payments, including base rent charges of $0.4 million per year, subject to periodic rent increases, and the Company's proportionate share of operating expenses.

In June 2022, the Company entered into a two-year noncancelable agreement for dedicated laboratory and office space in Newton, Massachusetts (the "Newton, MA Lease"), which was amended in September 2022. Pursuant to the amended Newton, MA Lease, the

Company entered into a two-year noncancelable agreement for new dedicated laboratory and office space in Newton, Massachusetts, on the same campus as, and in lieu of, the space leased under the original lease. The Company took occupancy of the new dedicated laboratory and office space in December 2022. The amended Newton, MA Lease provided for monthly rental payments, including base rent charges of $1.3 million per year. In August 2024, the Newton, MA Lease was further amended to extend the lease through November 2025, with an option to further extend the lease for an additional twenty-five months or continue the lease on a month-to-month basis after completion of the term ending in November 2025.

The components of operating lease expense were as follows (in thousands):

	For the Three Months Ended September 30, 2024	For the Three Months Ended September 30, 2023	For the Nine Months Ended September 30, 2024	For The Nine Months Ended September 30, 2023
Lease cost:				
Operating lease cost	$ 440	$ 430	$ 1,301	$ 1,290
Variable lease cost	4	11	11	34
Total lease cost	$ 444	$ 441	$ 1,312	$ 1,324
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows related to operating leases	$ 435	$ 432	$ 1,304	$ 1,296

Future minimum lease payments under the noncancelable leases as of September 30, 2024 was as follows (in thousands):

Year Ending December 31,	Operating Lease
2024 (excluding the nine months ended September 30, 2024)	437
2025	1,246
Total lease payments	1,683
Present value adjustment	(50)
Present value of operating lease liability	$ 1,633

As of September 30, 2024, the Company's operating leases were measured using a weighted-average incremental borrowing rate of 6.0% over a weighted-average remaining lease term of 1.1 years.

As of September 30, 2023, the Company's operating leases were measured using a weighted-average incremental borrowing rate of 6.0% over a weighted-average remaining lease term of 2.0 years.

The total operating liabilities are presented on the Company's condensed consolidated balance sheet based on maturity dates. $1.4 million is classified under "operating lease liabilities, current" for the portion due within twelve months, and $0.2 million is classified under "operating lease liabilities, non-current".

License Agreements

The Company has entered into license agreements with Adimab and WuXi Biologics (see Note 7).

Other Agreements

In November 2022, the Company entered into the PHP MSA (see Note 8). Concurrently with the PHP MSA, the Company entered into the PHP Work Order, pursuant to which PHP agreed to advise and counsel the Company regarding clinical development and regulatory matters with respect to its product candidates. The PHP Work Order was effective for six months from November 2022 and terminated in accordance with its terms in May 2023. As compensation for the services and deliverables under the PHP Work Order, the Company recognized research and development expense of $0.5 million per month during the term of the PHP Work Order for an Aggregate Fee of $3.0 million.

Manufacturing Agreements

In December 2020, the Company entered into a Commercial Manufacturing Services Agreement with WuXi Biologics, which was amended and restated in August 2021 and further amended and restated in September 2023 (as amended and restated, the "Commercial Manufacturing Agreement"). The Commercial Manufacturing Agreement outlines the terms and conditions under which WuXi Biologics manufactures drug substance and drug product for commercial use.

Through September 30, 2024, the Company committed to noncancelable purchase obligations related to commercial drug substance and drug product manufacturing under the Commercial Manufacturing Agreement. As of September 30, 2024, the total remaining contractually binding commercial drug substance and drug product purchase obligations due to WuXi Biologics was $38.3 million, which is expected to be paid in 2024 and 2025. As of September 30, 2024, $36.5 million related to the contractually binding commercial drug substance and drug product batches was included in accounts payable and accrued expenses, which is expected to be paid in 2024 and 2025.

Through September 30, 2024, the Company committed to noncancelable purchase obligations related to the procurement of materials to be used in future drug substance and drug product manufacturing under the Commercial Manufacturing Agreement. As of September 30, 2024, the total remaining contractually binding purchase obligations due to WuXi Biologics was $17.0 million, which is expected to be paid in 2024 and 2025. As of September 30, 2024, $10.6 million related to the procurement of materials to be used in future drug substance and drug product manufacturing was included in accounts payable and accrued expenses, which is expected to be paid in 2024 and 2025.

Unless earlier terminated, the Commercial Manufacturing Agreement remains in effect for an initial period of five years from the date of the last amendment and restatement of the agreement and thereafter automatically renews for further successive periods of five years each. Either party may terminate the agreement upon the breach or default by the other party, other than a non-payment breach, that is not timely cured after notice thereof. Both parties are also entitled to terminate the Commercial Manufacturing Agreement if the other party becomes insolvent or is the subject of a petition in bankruptcy or of any other related proceeding or event. Either party may terminate either the Commercial Manufacturing Agreement in its entirety, or an individual order, (i) to the extent the other party suffers a force majeure event that is continuing for a predefined period of time and (ii) if the other party fails to make a payment when due under the arrangement and such non-payment is not timely cured after notice thereof. Until regulatory approval and future economic benefit is probable, the Company will continue to expense costs related to batches manufactured under the Commercial Manufacturing Agreement.

Other Contracts

The Company enters into agreements with third parties in the ordinary course of business for various products and services, including those related to research, preclinical and clinical operations, manufacturing and support, supply chain, and distribution. These contracts do not contain any material minimum purchase commitments. Certain of these agreements provide for termination rights subject to the payment of termination fees and/or wind-down costs. Under such agreements, the Company is contractually obligated to make certain payments to vendors upon early termination, primarily to reimburse them for their unrecoverable outlays incurred prior to cancellation as well as any amounts owed by the Company prior to early termination. The actual amounts the Company could pay in the future to the vendors under such agreements may differ from the purchase order amounts due to cancellation provisions. The termination fees were not probable of payment as of September 30, 2024 and December 31, 2023.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings or other litigation relating to claims arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and estimated exposure amount. Legal fees and other costs associated with such proceedings are expensed as incurred.

On January 31, 2023, a securities class action lawsuit captioned Brill v. Invivyd, Inc., et. al., Case No. 1:23-CV-10254-LTS, was filed against the Company and certain of its former officers in the U.S. District Court for the District of Massachusetts. The complaint alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder on the basis of purportedly materially false and misleading statements and omissions concerning ADG20's effectiveness against the Omicron variant of COVID-19. The complaint sought, among other things, unspecified damages, attorneys' fees, expert fees, and other costs. The court appointed lead plaintiffs for the action on June 28, 2023. On August 23, 2023, the lead plaintiffs filed an amended complaint that made allegations similar to those in the original complaint and asserted the same claims against the same defendants as the original complaint. On October 19, 2023, the parties filed a joint stipulation to advise the court that the lead plaintiffs intended to seek leave to file a second amended complaint, and on November 22, 2023, the lead plaintiffs filed a second amended complaint that made allegations similar to those in the prior complaints and asserted the same claims against the same defendants as the prior complaints. On January 12, 2024, the defendants filed a motion to dismiss the second amended complaint in its entirety. The lead plaintiffs filed an opposition to the motion to dismiss on February 26, 2024, and the defendants filed a reply in further support of their motion to dismiss on March 27, 2024. The court heard oral arguments on the defendants' motion to dismiss on May 10, 2024. The court granted the defendants' motion to dismiss on September 18, 2024, dismissing the second amended complaint in its entirety, with prejudice and without leave to amend. The plaintiffs did not appeal the court's decision. As such, the Company has concluded that this matter is closed.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to its vendors, lessors, contract research organizations, contract development and manufacturing organizations ("CDMOs"), business partners and other parties

with respect to certain matters, including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or executive officers. The maximum potential amount of future payments that the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

10. Common Stock

Shares Reserved for Future Issuance

As of September 30, 2024, the Company had reserved 45,909,485 shares of common stock for the exercise of outstanding stock options and the issuance of awards available for grant under the Company's 2020 Equity Incentive Plan, 2021 Equity Incentive Plan and 2021 Employee Stock Purchase Plan (see Note 11).

Shelf Registration Statement

In September 2022, the Company filed a shelf registration statement on Form S-3 with the SEC (File No. 333-267643) and an accompanying base prospectus, which was declared effective by the SEC on October 5, 2022, for the offer and sale of up to $400 million of the Company's securities. As of September 30, 2024, $325 million of the Company's securities remained available for offer and sale under this shelf registration statement.

ATM Facility

In December 2023, the Company entered into a Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor"), pursuant to which the Company may, at its option, offer and sell shares of its common stock, with a sales value of up to $75.0 million, from time to time, through Cantor, acting as sales agent, in transactions deemed to be "at the market offerings", as defined in Rule 415 under the Securities Act of 1933, as amended. Cantor is entitled to a commission of 3% of the gross proceeds from any sales of such shares.

In February 2024, the Company sold 9,000,000 shares of its common stock under the Sales Agreement at an average price of $4.50 per share for $39.3 million in net proceeds. As of September 30, 2024, $34.5 million remained available for sale under the Sales Agreement.

Treasury Stock

In March 2023, the Company repurchased, and subsequently retired, 206,802 shares of unvested restricted common stock at the original purchase price upon a termination of service of an employee during the vesting period. The fair value of the repurchased common stock was insignificant. Upon retirement, the shares were redesignated as authorized but unissued shares of the Company's common stock.

In May 2023, the Company repurchased 46,600 shares of unvested restricted common stock at the original purchase price upon a termination of service of an employee during the vesting period. The shares of common stock repurchased were recorded as treasury stock. The fair value of the repurchased common stock was insignificant. In June 2023, the Company retired the 46,600 shares of treasury stock. Upon retirement, the shares were redesignated as authorized but unissued shares of the Company's common stock.

In October 2023, the Company repurchased 31,765 shares of unvested restricted common stock at the original purchase price upon a termination of service of an employee during the vesting period. The shares of common stock repurchased were recorded as treasury stock. The fair value of the repurchased common stock was insignificant. In December 2023, the Company retired the 31,765 shares of treasury stock. Upon retirement, the shares were redesignated as authorized but unissued shares of the Company's common stock.

11. Stock-Based Compensation

2020 Equity Incentive Plan

The Company's 2020 Equity Incentive Plan (the "2020 Plan") provides for the Company to grant incentive stock options, non-qualified stock options, restricted stock awards, restricted stock units and other stock-based awards to employees, members of the board of directors and consultants. The 2020 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The board of directors may also delegate to one or more officers of the Company the power to grant awards to employees and certain officers of the Company. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or its committee or any such officer if so delegated.

The exercise price for stock options granted may not be less than the fair market value of the Company's common stock on the date of grant, as determined by the board of directors, or at least 110% of the fair market value of the Company's common stock on the date of grant in the case of an incentive stock option granted to an employee who owns stock representing more than 10% of the voting power of all classes of stock as determined by the board of directors as of the date of grant. Prior to the IPO, the Company's board of directors determined the fair value of the Company's common stock, taking into consideration its most recently available valuation of

common stock performed by third parties as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant. Stock options granted under the 2020 Plan expire after ten years and typically vest over a four-year period with the first 25% vesting upon the first anniversary of a specified vesting commencement date and the remainder vesting in 36 equal monthly installments over the succeeding three years, contingent on the recipient's continued employment or service. Certain awards of stock options permit the holders to exercise the option in whole or in part prior to the full vesting of the option in exchange for unvested shares of restricted common stock with respect to any unvested portion of the option so exercised.

As of September 30, 2024, there were 2,985,456 shares authorized to be issued upon the exercise of outstanding stock option grants and no shares reserved for future issuance under the 2020 Plan.

2021 Equity Incentive Plan

In July 2021, the Company's board of directors adopted, and its stockholders approved, the 2021 Equity Incentive Plan (the "2021 Plan"), which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to the Company's IPO. The 2021 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares reserved for issuance under the 2021 Plan was equal to 35,075,122, which is the sum of 11,413,572 new shares; plus the number of shares (not to exceed 23,661,550 shares), which represents (i) the number of shares that remained available for issuance under the 2020 Plan, at the time the 2021 Plan became effective, and (ii) any shares subject to outstanding stock options or other stock awards that were granted under the 2020 Plan that are forfeited, terminate, expire or are otherwise not issued. In addition, the number of shares of the Company's common stock reserved for issuance under the 2021 Plan will automatically increase on the first day of each calendar year pursuant to the evergreen provision thereof, beginning on January 1, 2022 and continuing through January 1, 2031, in an amount equal to 5% of the shares of common stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the board of directors. On January 1, 2022, 5,539,145 shares of common stock were automatically added to the shares authorized for issuance under the 2021 Plan pursuant to the evergreen provision thereof. The number of shares to be issued under the 2021 Plan did not increase on January 1, 2023 as determined by the Company's board of directors. On January 1, 2024, 3,304,820 shares of common stock were added to the shares authorized for issuance under the 2021 Plan, pursuant to the evergreen provision thereof, as determined by the Company's board of directors. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, repurchased or are otherwise terminated by the Company under the 2021 Plan will be added back to the shares of common stock available for issuance under the 2021 Plan.

As of September 30, 2024, there were an aggregate of 45,004,758 shares authorized to be issued under the 2020 Plan and the 2021 Plan, which included 2,985,456 and 18,890,298 shares authorized to be issued upon the exercise of outstanding stock option grants from the 2020 Plan and 2021 Plan, respectively, and 0 and 23,129,004 shares reserved for future issuance under the 2020 Plan and 2021 Plan, respectively.

Stock Option Valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. Prior to its IPO in August 2021, the Company had been a private company. Due to the proximity to the IPO, the Company continues to lack sufficient company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table presents, on a weighted-average basis, the assumptions used in the Black-Scholes option-pricing model to determine the grant date fair value of stock options granted:

	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Expected term (in years)	6.1	6.1	5.9	5.9
Expected volatility	61.8%	64.3%	62.5%	68.0%
Risk-free interest rate	4.1%	4.2%	4.1%	3.7%
Expected dividend yield	—%	—%	—%	—%

Stock Option Activity

The following table summarizes the Company's stock option activity since December 31, 2023:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	23,065,514	$ 5.08	8.7	$ 24,745
Granted	5,866,869	$ 3.42	—	—
Exercised	(296,301)	$ 0.96	—	—
Forfeited	(6,760,328)	$ 4.70	—	—
Outstanding at September 30, 2024	21,875,754	$ 4.81	7.8	$ 93
Vested and expected to vest at September 30, 2024	21,875,754	$ 4.81	7.8	$ 93
Options exercisable at September 30, 2024	11,506,753	$ 5.98	6.9	$ 93

The weighted-average grant date fair value of stock options granted during the three and nine months ended September 30, 2024 was $0.74 and $2.06, respectively, per share. The weighted-average grant date fair value of stock options granted during the three and nine months ended September 30, 2023 was $1.06 and $1.15, respectively, per share.

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair market value of the common stock for the options that had exercise prices lower than the estimated fair value of the Company's common stock at September 30, 2024 and 2023.

The total intrinsic value of stock options exercised was $0.1 million and $0.3 million for the three and nine months ended September 30, 2024, respectively. The total intrinsic value of stock options exercised was $0.1 million and $0.5 million for the three and nine months ended September 30, 2023, respectively.

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense (service-based stock options and employee stock purchase plan) in the following expense categories of its condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Research and development	$ 932	$ 1,235	$ 3,497	$ 5,116
Selling, general and administrative	1,934	3,029	13,234	9,225
	$ 2,866	$ 4,264	$ 16,731	$ 14,341

As of September 30, 2024, $0.9 million of share-based compensation expense was capitalized and recorded as Inventory in the accompanying condensed consolidated balance sheet.

In April 2024, David Hering ceased serving as the Company's Chief Executive Officer and as a member of the Company's board of directors. Pursuant to his separation agreement, the Company recognized approximately $5.5 million of selling, general, and administrative related stock-based compensation expense associated with the accelerated vesting of a portion of his outstanding stock options, in accordance with the terms of his employment agreement.

As of September 30, 2024, total unrecognized stock-based compensation expense related to unvested stock-based awards was $21.5 million, which is expected to be recognized over a weighted-average period of 2.3 years.

2021 Employee Stock Purchase Plan

In July 2021, the Company's board of directors adopted, and its stockholders approved, the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to the Company's IPO. A total of 1,342,773 shares of common stock were initially reserved for issuance under the 2021 ESPP. There were 438,046 shares issued under the 2021 ESPP as of September 30, 2024. The number of shares of common stock that may be issued under the 2021 ESPP will automatically increase on the first day of each calendar year, pursuant to the evergreen provision thereof, beginning on January 1, 2022 and continuing through January 1, 2031, by an amount equal to the lesser of (i) 1% of the shares of common stock outstanding on the last day of the calendar month before the date of each automatic increase, (ii) 2,685,546 shares and (iii) an amount determined by the Company's board of directors. The number of shares to be issued under the 2021 ESPP did not increase on January 1, 2024 or January 1, 2023, pursuant to the evergreen provision thereof, as determined by the Company's board of directors. The first offering under the 2021 ESPP was June 6, 2022. As of September 30, 2024, 904,727 shares remained available for issuance under the 2021 ESPP. During both the three and nine months ended September 30, 2024, the Company recognized less than $0.1 million

in related stock-based compensation expense. During both the three and nine months ended September 30, 2023, the Company recognized less than $0.1 million in related stock-based compensation expense.

Warrant Expense

In November 2022, the Company entered into the PHP MSA, the PHP Work Order and a warrant agreement with respect to the PHP Warrant. To compensate for the services and deliverables provided by PHP, the Company issued 6,824,712 equity-classified warrants to PHP. Each warrant shall give the right to acquire common stock of the Company at a purchase price of $3.48 per share. Per the agreement, the PHP Warrant is exercisable upon either the achievement of corresponding market capitalization targets or a consummation of a fundamental transaction (as defined in the PHP Warrant); as such, there are no other requirements, including any continuous service requirements, in order for PHP to be entitled to the PHP Warrant, if and when any portion of it vests.

The aggregate grant date fair value of the PHP Warrant was $17.4 million, which was recognized as warrant expense on the grant date in November 2022.

There were no warrants issued during the three and nine months ended September 30, 2024 and 2023. As of September 30, 2024, there were 6,824,712 warrants outstanding and not yet vested at a weighted-average exercise price of $3.48, with a weighted-average remaining contractual term of 8.13 years.

12. Income Taxes

For the three and nine months ended September 30, 2024 and 2023, the Company recorded no income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each period, due to its uncertainty of realizing a benefit from those items. Substantially all of the Company's operating losses since inception have been generated in the U.S.

13. Defined Contribution Plan

The Company maintains a 401(k) Plan (the "401(k) Plan") for the benefit of eligible employees. The 401(k) Plan is a defined contribution plan under Section 401(k) of the Internal Revenue Code of 1986, as amended, that covers all 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. Pursuant to the terms of the 401(k) Plan, the Company is required to make non-elective contributions of 3% of eligible participants' compensation. For the three and nine months ended September 30, 2024, the Company contributed $0.2 million and $0.5 million, respectively, to the 401(k) Plan. For the three and nine months ended September 30, 2023, the Company contributed $0.3 million and $0.6 million, respectively, to the 401(k) Plan.

14. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Numerator:				
Net loss attributable to common stockholders	$ (60,739)	$ (39,440)	$ (151,482)	$ (124,989)
Denominator:				
Weighted-average common shares outstanding, basic and diluted	119,495,284	109,754,812	118,163,599	109,333,684
Net loss per share attributable to common stockholders, basic and diluted	$ (0.51)	$ (0.36)	$ (1.28)	$ (1.14)

Shares of unvested restricted common stock are not considered outstanding for accounting purposes until vested and were excluded from the calculations of basic net loss per share attributable to common stockholders for the three and nine months ended September 30, 2023. There were no shares of unvested restricted common stock for the three and nine months ended September 30, 2024.

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential

common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated, because including them would have had an anti-dilutive effect:

	For the Three and Nine Months Ended September 30, 2024	For the Three and Nine Months Ended September 30, 2023
Stock options to purchase common stock	21,875,754	22,046,348
Unvested restricted common stock	—	31,766
Warrants to purchase common stock	6,824,712	6,824,712
	28,700,466	28,902,826

15. Related-Party Transactions

As of September 30, 2024 and December 31, 2023, an aggregate of $1.3 million and $0.7 million, respectively, was due to Adimab under the Adimab Assignment Agreement, the Adimab Collaboration Agreement, the Adimab Platform Transfer Agreement and the Adimab DNA Sequencing Services Agreement (as defined below) by the Company and was included in accrued expenses. As of September 30, 2024 and December 31, 2023, no amounts were due to the Company from Adimab under the Adimab Assignment Agreement, the Adimab Collaboration Agreement, the Adimab Platform Transfer Agreement or the Adimab DNA Sequencing Services Agreement.

Adimab Assignment Agreement

Under the Adimab Assignment Agreement, Adimab, a principal stockholder of the Company, is entitled to receive milestone and royalty payments upon specified conditions and receives payments from the Company for providing ongoing services under the agreement (see Note 7).

During both the three and nine months ended September 30, 2024, the Company did not recognize any IPR&D expense with respect to contingent consideration payable under the Adimab Assignment Agreement. During the three and nine months ended September 30, 2023, the Company recognized $3.2 million and $3.6 million, respectively, as IPR&D expense with respect to a milestone payable under the Adimab Assignment Agreement.

During the three and nine months ended September 30, 2024 and 2023, the Company did not recognize any research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab Assignment Agreement.

During both the three and nine months ended September 30, 2024, the Company expensed $0.5 million of royalties as costs of product revenue and reserves all rights under the Adimab Assignment Agreement and the applicable law. During both the three and nine months ended September 30, 2023, the Company did not recognize any costs of product revenue with respect to royalties under the Adimab Assignment Agreement.

Adimab Collaboration Agreement

Under the Adimab Collaboration Agreement, the Company is obligated to pay Adimab for certain fees, milestones and royalty payments (see Note 7).

During the three and nine months ended September 30, 2024, the Company recognized $0.6 million and $1.8 million, respectively, of research and development expense related to the quarterly fee under the Adimab Collaboration Agreement. During the three and nine months ended September 30, 2023, the Company recognized $1.3 million and $3.9 million, respectively, of research and development expense related to the quarterly fee under the Adimab Collaboration Agreement.

During both the three and nine months ended September 30, 2024, the Company did not recognize any research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab Collaboration Agreement. During the three and nine months ended September 30, 2023, the Company recognized $0.1 million and $0.5 million, respectively, of research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab Collaboration Agreement.

During both the three and nine months ended September 30, 2024, the Company did not recognize any IPR&D expense related to an option fee. During both the three and nine months ended September 30, 2023, the Company recognized $1.0 million of IPR&D expense related to an option exercise fee.

During both the three and nine months ended September 30, 2024, the Company did not recognize any IPR&D expense related to a drug delivery fee or optimization fee. During both the three and nine months ended September 30, 2023, the Company recognized $0.2 million of IPR&D expense related to a drug delivery fee and $0.2 million of IPR&D expense related to an optimization completion fee.

Adimab Platform Transfer Agreement

Under the Adimab Platform Transfer Agreement, the Company is obligated to pay Adimab for certain fees, milestones and royalty payments (see Note 7), including an annual fee of single digit millions on each of the first four anniversaries of the Adimab Platform Transfer Agreement Effective Date.

During both the three and nine months ended September 30, 2024 and 2023, the Company recognized a portion of the annual fee as research and development expense under the Adimab Platform Transfer Agreement.

Adimab DNA Sequencing Services Agreement

In May 2023, as amended in January 2024, the Company entered into a Services Agreement with Adimab for Adimab to perform DNA sequencing on yeast samples provided by the Company, and the delivery of the resulting data and information to the Company (the "Adimab DNA Sequencing Services Agreement"). In exchange for the services performed, the Company will pay Adimab a fee for each yeast-derived DNA template sample present in the well within the sequencer plate.

During both the three and nine months ended September 30, 2024, the Company recognized less than $0.1 million of research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab DNA Sequencing Services Agreement. During both the three and nine months ended September 30, 2023, the Company recognized less than $0.1 million of research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab DNA Sequencing Services Agreement

Population Health Partners, L.P.

Under the PHP MSA and PHP Work Order, the Company was obligated to pay cash compensation for services and deliverables (see Note 8). Tamsin Berry, a member of the Company's board of directors, is a Limited Partner of PHP.

During the three and nine months ended September 30, 2024, the Company did not recognize any research and development expense related to the cash compensation paid to PHP. During the three and nine months ended September 30, 2023, the Company recognized $0 and $2.3 million, respectively, of research and development expense related to services performed by PHP in connection with the PHP Work Order, which terminated in accordance with its terms in May 2023.

As of September 30, 2024, no amounts were due to PHP by the Company, and no amounts were due from PHP to the Company.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission ("SEC") on March 28, 2024 (the "2023 Form 10-K"). Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "we," "us," and "our" refer to Invivyd, Inc. together with its consolidated subsidiaries.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include, but are not limited to, statements regarding our management team's expectations, hopes, beliefs, intentions or strategies regarding the future, projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, and are not guarantees of future performance. The words "may," "anticipate," "believe," "could," "expect," "intends," "might," "plan," "possible," "potential," "aim," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These statements speak only as of the date of this Quarterly Report on Form 10-Q and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. 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 include, without limitation, statements about the following:

- our plans related to the commercialization of PEMGARDA™ (pemivibart), which received emergency use authorization ("EUA") from the U.S. Food and Drug Administration ("FDA") in March 2024;
- our expectation that PEMGARDA will be our first monoclonal antibody ("mAb") in a planned series of innovative mAb candidates designed to keep pace with SARS-CoV-2 viral evolution, and our plans to leverage our INVYMAB™ platform approach to periodically introduce new or engineered mAb candidates as the SARS-CoV-2 virus evolves over time;
- the anticipated timing, design, progress and results of preclinical studies and clinical trials of our product candidates, such as pemivibart and VYD2311, including statements regarding initiation or completion of studies or trials and related preparatory work, the period during which results of any studies or trials will become available, and potential regulatory submissions;
- our commitment to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2, and our aim to develop a continuous repertoire of SARS-CoV-2 neutralizing mAbs to keep pace with viral evolution;
- our expectations related to general alignment with the FDA on an expedient, repeatable immunobridging pathway to future potential EUAs for serial, novel mAbs for the prevention and treatment of symptomatic COVID-19;
- our plans regarding submission of any applications for regulatory authorization or approval of our product candidates, including our July 2024 submission of a request to the FDA to amend the EUA for PEMGARDA for the treatment of mild-to-moderate symptomatic COVID-19 in certain immunocompromised patients utilizing a rapid immunobridging pathway, and our expectations regarding potential scope and timing thereof;
- our expectations regarding our ability to obtain and maintain regulatory authorizations or approvals for, our product candidates;
- our plans regarding SARS-CoV-2 variant monitoring of antiviral activity as part of our ongoing industrial virology effort;
- our expectations regarding the size of the patient populations, market acceptance and opportunity for and clinical utility of our product candidates, if authorized or approved for commercial use;
- our manufacturing capabilities and strategy;
- our ability to successfully commercialize our product candidates, if authorized or approved, including our distribution capabilities and strategy;
- our ability to leverage technology and our INVYMAB platform approach to identify and develop future product candidates;
- our expectation to apply our INVYMAB platform approach to produce lead molecules for other viral diseases, such as influenza;

- our estimates of our expenses, ongoing losses, future potential revenue, capital requirements and our need for or ability to obtain additional funding;
- our expectations regarding our ability to continue as a going concern; and
- our competitive position and the development of and projections relating to our competitors or our industry.

The foregoing list of forward-looking statements is not exhaustive. You should refer to the "Risk Factors" sections of the 2023 Form 10-K and this Quarterly Report on Form 10-Q for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Other sections of this Quarterly Report on Form 10-Q may include additional factors that could harm our business and financial performance. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report on Form 10-Q will prove to be accurate. 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. You should, however, review the factors and risks and other information we describe in the reports we file from time to time with the SEC.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

Overview

Invivyd, Inc. is a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2. Our proprietary INVYMAB™ platform approach combines state-of-the-art viral surveillance and predictive modeling with advanced antibody engineering. INVYMAB is designed to facilitate the rapid, serial generation of new monoclonal antibodies ("mAbs") to address evolving viral threats.

On March 22, 2024, we received emergency use authorization ("EUA") from the U.S. Food and Drug Administration ("FDA") for PEMGARDA™ (pemivibart) injection, for intravenous use, a half-life extended investigational mAb, for the pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. Recipients should not be currently infected with or have had a known recent exposure to an individual infected with SARS-CoV-2.

In July 2024, we submitted a request to the FDA to amend the EUA for PEMGARDA, for the treatment of mild-to-moderate symptomatic COVID-19 in certain immunocompromised patients. The submission utilizes a rapid immunobridging pathway previously aligned in principle with the FDA. The EUA amendment request is based on positive immunobridging analyses of pemivibart versus comparator mAbs and data from our ongoing CANOPY Phase 3 clinical trial in participants with moderate-to-severe immune compromise. The COVID-19 treatment EUA request focuses on the critical treatment needs of people in the U.S. who have moderate-to-severe immune compromise and for whom alternative COVID-19 treatment options are not clinically appropriate or accessible.

PEMGARDA is our first mAb in a planned series of innovative mAb candidates designed to keep pace with SARS-CoV-2 viral evolution. As the SARS-CoV-2 virus evolves over time, we anticipate leveraging our INVYMAB platform approach to periodically introduce new or engineered mAb candidates, an approach that would be analogous to the periodic updates made to influenza and COVID-19 vaccines. In January 2024, we nominated VYD2311, a next generation mAb candidate for COVID-19, as a drug candidate, and in September 2024, we announced dosing of the first participants in a Phase 1 clinical trial of VYD2311. VYD2311 is a mAb with high in vitro neutralization potency shown against prominent SARS-CoV-2 variants tested to date. The Phase 1 randomized, blinded, placebo-controlled clinical trial will evaluate escalating dosing as well as safety, tolerability, pharmacokinetics and immunogenicity of VYD2311 in healthy trial participants. The Phase 1 clinical trial is being conducted in Australia and will evaluate multiple dose levels of VYD2311 through various routes of administration, including exploration of intramuscular administration and subcutaneous administration, which are designed to be more system- and patient-friendly than intravenous administration. We expect preliminary data readouts from the Phase 1 clinical trial late in the fourth quarter of 2024 and anticipate additional clinical readouts from the VYD2311 program throughout 2025. Like pemivibart, VYD2311 was engineered from adintrevimab, our investigational mAb that has a robust safety data package and demonstrated clinically meaningful results in global Phase 2/3 clinical trials for both the prevention and treatment of COVID-19.

In May 2024, we announced general alignment with the FDA on an expedient, repeatable immunobridging pathway to future potential EUAs for serial, novel mAbs for the prevention and treatment of symptomatic COVID-19. This pathway provides us with the opportunity to rapidly, efficiently, and durably deliver high value medicines that prevent and treat symptomatic COVID-19 in vulnerable

populations. In addition to developing candidates for COVID-19, we expect to apply our INVYMAB platform approach to produce lead molecules for other viral diseases, such as influenza.

Globally, COVID-19 has caused millions of deaths and lasting health problems in many survivors and remains a significant global health concern, particularly for immunocompromised individuals. Isolation and mental health impacts, absenteeism from work, and educational losses for children have been profound consequences of this crisis. COVID-19 persists and continues to impact patients, notably those who are immunocompromised, and combating this disease will require a variety of effective and safe prevention and treatment options for years to come. By leveraging our capabilities, which we have developed through our experience with adintrevimab and pemivibart and over four years in the COVID-19 space, we aim to develop a continuous repertoire of SARS-CoV-2 neutralizing mAbs to keep pace with viral evolution.

PEMGARDA has not been approved but has been authorized for emergency use by the FDA under an EUA, for pre-exposure prophylaxis of COVID-19 in certain adults and adolescent individuals (12 years of age and older weighing at least 40 kg). The emergency use of PEMGARDA is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner. PEMGARDA is authorized for use only when the combined national frequency of variants with substantially reduced susceptibility to PEMGARDA is less than or equal to 90%, based on available information including variant susceptibility to PEMGARDA and national variant frequencies.

We engage in active SARS-CoV-2 variant monitoring of antiviral activity as part of our ongoing industrial virology effort, which leverages a consistent, high-quality, independent, third-party pseudoviral system that routinely tests authentic Invivyd-produced molecules and is supported by structure-based analytics. In September 2024, we announced continued neutralizing activity of PEMGARDA (pemivibart) against SARS-CoV-2 variants KP.3.1.1 and LB.1, and attractive neutralization potency of VYD2311 against the same contemporary viruses, and also provided an update to ongoing structural analysis showing no meaningful mutational change in the pemivibart binding site since the Omicron shift late in 2021.

Since our inception, we have devoted substantially all of our resources to organizing and staffing, building an intellectual property portfolio, business planning, conducting research and development, establishing and executing arrangements with third parties for the manufacture of our product candidates, and raising capital. Our focus in recent months has been and will continue to be supporting the commercialization of PEMGARDA and establishing streamlined development pathways that could enable us to efficiently introduce new or engineered mAb candidates targeting SARS-CoV-2, leveraging our INVYMAB platform approach and previously generated safety and efficacy data from our clinical trials of adintrevimab and/or pemivibart, including pursuit of a potential EUA for COVID-19 treatment in certain immunocompromised people utilizing a rapid immunobridging pathway.

We rely on partnerships, external consultants and contract research organizations ("CROs") to conduct discovery, nonclinical, preclinical, clinical and commercial activities. Additionally, we rely on contract testing laboratories and a contract development and manufacturing organization ("CDMO") to execute our chemistry, manufacturing and controls development, testing and manufacturing activities. We have engaged WuXi Biologics (Hong Kong) Limited ("WuXi Biologics"), a CDMO, for the development and manufacture of our product candidates for clinical and commercial use. Further, in 2022, we secured dedicated laboratory space and expanded our research team in order to enable internal discovery and development of our mAb candidates, while continuing to leverage our existing partnership with Adimab, LLC ("Adimab"). We are focused on antibody discovery and use of Adimab's platform technology, while building our internal capabilities. In addition, we expect to continue to rely on third parties for clinical trials and the manufacture and testing of our product candidates, as well as to perform ongoing research and development and other services on our behalf.

Since our inception, we have financed our operations primarily with net proceeds of $464.7 million from sales of our preferred stock, with net proceeds of $327.5 million from our initial public offering ("IPO"), and with net proceeds of $39.3 million from sales of our common stock under the Sales Agreement (as defined below). After receiving EUA in March 2024, we have also funded our operations from sales of PEMGARDA. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and commercialization of one or more of our product candidates, as they become authorized or approved.

Since our inception, we have incurred significant losses, including a net loss of $151.5 million for the nine months ended September 30, 2024. As of September 30, 2024, we had an accumulated deficit of $883.6 million. We may continue to incur significant expenses and recognize losses in the foreseeable future as we expand and progress our research and development activities, manufacturing activities and commercialization efforts. In addition, our losses from operations may fluctuate significantly from period to period depending on the timing of our clinical trials and our expenditures on other research and development activities, manufacturing activities, and commercialization efforts. Our expenses could increase substantially in connection with our ongoing activities, as we:

- commercialize PEMGARDA;
- initiate and conduct clinical trials of our product candidates;
- develop product candidates in any new indications or patient populations;

- advance our preclinical and discovery programs, including development and screening of additional antibodies, as well as ongoing SARS-CoV-2 variant monitoring and testing;
- seek regulatory authorization or approval for any product candidates that successfully complete clinical trials;
- pursue coverage and reimbursement for our product candidates, if authorized or approved;
- acquire or in-license other product candidates, intellectual property and/or technologies;
- further develop and validate our commercial-scale current Good Manufacturing Practices ("cGMP") manufacturing process and manufacture material under cGMP at our contracted manufacturing facilities for clinical trials and commercial sales;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- comply with regulatory requirements established by the applicable regulatory authorities;
- maintain and expand a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain regulatory authorization or approval;
- hire and retain personnel, including research, clinical, development, manufacturing, quality control, quality assurance, regulatory, scientific and other personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

On March 22, 2024, we received EUA from the FDA for PEMGARDA, and as such, we will continue to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution.

As a result, we will require additional funding through a combination of contribution from revenues, equity offerings, government or private-party grants, debt financings or other capital sources, such as collaborations with other companies, strategic alliances or licensing arrangements to support our continuing operations and pursue our growth strategy. We may be unable to secure additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we are unable to secure additional funding when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

Because of the numerous risks and uncertainties associated with pharmaceutical product development and emergence of SARS-CoV-2 variants, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. We may never obtain regulatory authorization or approval for any of our product candidates other than PEMGARDA. Even with product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Based on current operating plans and excluding any contribution from future revenues or external financing, we will not have sufficient cash and cash equivalents to fund our operating expenses and capital requirements beyond one year from the issuance date of the interim condensed consolidated financial statements in this Quarterly Report on Form 10-Q, and therefore, we have concluded that there is substantial doubt about our ability to continue as a going concern. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See the section entitled "Liquidity and Capital Resources" for more information.

Components of Our Results of Operations

Product Revenue, Net

In March 2024, we received EUA from the FDA for PEMGARDA. Product revenue, net consists of product revenue earned on the sales of PEMGARDA in the United States.

Cost of Product Revenue

Cost of product revenue includes PEMGARDA manufacturing costs, labor and overhead costs, and stability study costs. PEMGARDA manufacturing costs include manufacturing materials, third-party manufacturing costs, packaging costs, shipping costs, and royalties.

Research and Development Expenses

The nature of our business and primary focus of our activities generates a significant amount of research and development costs. Research and development expenses represent costs incurred by us for:

- the nonclinical and preclinical development of our product candidates, including our discovery efforts;

- the procurement of our product candidates from a third-party manufacturer; and
- the global clinical development of our product candidates.

Such costs consist of:

- personnel-related expenses, including salaries, bonuses, benefits, third-party fees and other compensation-related costs, including stock-based compensation expense, for employees engaged in research and development functions;
- expenses incurred under agreements with third parties, such as collaborators, consultants, contractors and CROs, that conduct the discovery, nonclinical and preclinical studies and clinical trials of our product candidates and research programs;
- costs of procuring manufactured product candidates for use in nonclinical studies, preclinical studies, clinical trials and for commercial supply, prior to receiving authorization or approval, from a third-party CDMO;
- costs of outside consultants and advisors, including their fees and stock-based compensation;
- laboratory-related expenses, which include equipment, laboratory supplies, rent expense, depreciation expense, and other operating costs;
- payments made under third-party licensing agreements; and
- other expenses incurred as a result of research and development activities.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered.

Our primary focus since inception has been the development of antibodies against COVID-19. Our research and development costs consist primarily of external costs, such as fees paid to a CDMO, CROs and consultants in connection with our nonclinical studies, preclinical studies, clinical trials and product manufacturing. To date, external research and development costs for any individual product candidate have been tracked commencing upon product candidate nomination. We do not allocate employee-related costs, costs associated with our discovery efforts and other internal or indirect costs to specific research and development programs or product candidates because these resources are used and these costs are deployed across multiple programs under development and, as such, are not separately classified.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher and more variable development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Our research and development expenses will increase as we continue to advance PEMGARDA and as we expect to continue advancing VYD2311 through clinical development, including the associated manufacturing activities, pursue EUA or regulatory approval of our product candidates, and continue to discover and develop additional product candidates.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of any of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales or licensing of our product candidates. This is due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- filing acceptable IND applications with the FDA or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for our product candidates;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials, manufacture the product candidates and complete associated regulatory activities;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and successfully develop, obtain regulatory authorization or approval for our product candidates;
- successful enrollment and timely completion of clinical trials, including our ability to generate positive data from any such clinical trials;
- the costs associated with the development of any additional development programs and product candidates we identify in-house or acquire through collaborations;

- the prevalence, nature and severity of adverse events experienced with any product candidates;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder;
- our ability to obtain and maintain patent, trademark and trade secret protection and regulatory exclusivity for our product candidates, if and when approved, and otherwise protecting our rights in our intellectual property portfolio;
- our ability to maintain compliance with regulatory requirements, including current Good Clinical Practices, current Good Laboratory Practices and cGMPs, and to comply effectively with other rules, regulations and procedures applicable to the development and sale of pharmaceutical products;-
- timely receipt of regulatory authorizations or approvals from applicable regulatory authorities;
- potential significant and changing government regulation, regulatory guidance and requirements and evolving treatment guidelines; and
- the impact of any business interruptions to our operations or those of third parties with which we work, including as a result of any public health crisis.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others.

In emergency situations, such as a pandemic, and with a declaration of a public health emergency by the U.S. Secretary of the Department of Health and Human Services ("HHS"), the FDA has the authority to issue an EUA. While the COVID-19 public health emergency declared by HHS under the Public Health Service Act expired on May 11, 2023, this does not impact the FDA's ability to authorize COVID-19 drugs and biological products for emergency use. On March 22, 2024, we received EUA from the FDA for PEMGARDA. There can be no assurance that the public health emergency in the U.S. declared under the FDCA will continue to be in place for an extended period of time, that any of our other product candidates will be granted an EUA by the FDA, if we apply for such an authorization, or that we would be able to maintain an EUA, such as the EUA received for PEMGARDA, for an extended period of time. The emergency use of PEMGARDA is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564 of the FDCA, unless the declaration is terminated or authorization revoked sooner.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development ("IPR&D") expenses consist primarily of costs of contingent milestone payments incurred to acquire rights to Adimab's antibodies relating to COVID-19 and SARS and related intellectual property and a license to certain of Adimab's platform patents and technology (the "IPR&D assets") for use in the research and development of our product candidates. We expensed the cost of the IPR&D assets because they had no alternative future use as of the acquisition date. We will recognize additional IPR&D expenses in the future if and when it is deemed probable that we will make contingent milestone payments to Adimab under the terms of the agreement by which we acquired the IPR&D assets.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, bonuses, benefits, third-party fees and other compensation-related costs, including stock-based compensation, for our personnel and external contractors involved in our executive, finance, legal, business development and other administrative functions, as well as our commercial function. Selling, general and administrative expenses also include costs incurred for outside services associated with such functions, including legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; market research costs; and other selling, general and administrative expenses. These costs relate to the operation of the business, unrelated to the research and development function, or any individual program.

Our selling, general and administrative expenses will increase in the future as our business expands and we increase our headcount to support the expected growth in our research and development activities and the commercialization of any authorized or approved product candidates, such as PEMGARDA. We also anticipate increased expenses associated with operating as a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services, director and officer insurance premiums, and investor and public relations costs. We also expect to incur additional intellectual property-related expenses as we file additional patent applications to protect innovations arising from our research and development activities.

In June 2022, and subsequently amended in September 2022 and August 2024, we entered into a lease agreement for dedicated laboratory and office space in Newton, Massachusetts for research and development purposes. Through September 30, 2024, we have operated as a hybrid company with employees working at our corporate headquarters and remotely. We have not incurred material operating expenses for the rent, maintenance and insurance of facilities, or for the depreciation of fixed assets.

Other Income, Net

Other income, net consists of interest income earned from our cash, cash equivalents and marketable securities and the net amortization or accretion of premiums and discounts related to our marketable securities. We expect our interest income to vary each reporting period depending on our average bank deposits, money market funds and investment balances during the period and market interest rates.

Income Taxes

Since our inception, we have not recorded any income tax expense or realized benefits for the net losses we have incurred or for the research and development tax credits generated in each period as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credit carryforwards will not be realized.

We continue to monitor the manner in which countries will enact legislation to implement the Pillar Two framework proposed by the Organisation for Economic Co-operation and Development, which proposes a 15% global corporate minimum tax. As of September 30, 2024, various countries have enacted aspects of Pillar Two while committing to enact additional aspects in future years. While we do not expect these rules to have a material impact on our effective tax rate, we continue to monitor these initiatives on a global basis.

Results of Operations

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

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023:

(in thousands)	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Change
Revenue:			
Product revenue, net	$ 9,300	$ —	$ 9,300
Total revenue	9,300	—	9,300
Operating costs and expenses:			
Cost of product revenue	806	—	806
Research and development	57,850	25,574	32,276
Acquired in-process research and development	—	4,600	(4,600)
Selling, general and administrative	12,955	12,886	69
Total operating costs and expenses	71,611	43,060	28,551
Loss from operations	(62,311)	(43,060)	(19,251)
Other income:			
Other income, net	1,572	3,620	(2,048)
Total other income, net	1,572	3,620	(2,048)
Net loss	$ (60,739)	$ (39,440)	$ (21,299)

The following discussion presents the components of our expenses for the periods presented:

Product Revenue, Net

Product revenue, net was $9.3 million for the three months ended September 30, 2024. There was no product revenue, net for the three months ended September 30, 2023. The $9.3 million increase is the result of product sales in the third quarter of 2024 following the launch of PEMGARDA.

Cost of Product Revenue

Cost of product revenue was $0.8 million for the three months ended September 30, 2024. There was no cost of product revenue for the three months ended September 30, 2023. The $0.8 million increase is the result of PEMGARDA product sales following launch and certain period costs.

We began capitalizing our inventory costs in March 2024, in connection with EUA from the FDA and based upon our expectation that these costs would be recoverable through commercialization of PEMGARDA. Prior to the capitalization of our inventory costs, such costs were recorded as research and development expenses in the period incurred. Had our pre-EUA manufacturing costs been capitalized, our reported margins would approach 80%.

Research and Development Expenses

(in thousands)	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Change
Direct, external research and development expenses by program:			
VYD222[(1)]	$ 4,637	$ 12,327	$ (7,690)
VYD2311[(2)]	45,045	—	45,045
Adintrevimab	128	214	(86)
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	3,823	7,181	(3,358)
External discovery-related and other costs	4,217	5,852	(1,635)
Total research and development expenses	$ 57,850	$ 25,574	$ 32,276

[(1)] In March 2023, we announced the nomination of VYD222 as a novel mAb therapeutic option for COVID-19.
[(2)] In March 2024, we announced the nomination of VYD2311 as a novel mAb therapeutic option for COVID-19.

Research and development expenses were $57.9 million for the three months ended September 30, 2024, compared to $25.6 million for the three months ended September 30, 2023. The $32.3 million increase in research and development expenses was primarily due to the following:

- the decrease in direct costs related to our VYD222 program resulted from $4.3 million in contract costs for commercial manufacturing, $3.5 million in contract research costs for our CANOPY clinical trial, and $0.2 million in nonclinical expenses, partially offset by increases of $0.3 million in other external expenses;
- the increase in direct costs related to our VYD2311 program resulted from the nomination of our VYD2311 product candidate in the first quarter of 2024 and consisted primarily of contract manufacturing costs;
- the direct costs related to our adintrevimab program were consistent following the nomination of our VYD222 product candidate in the first quarter of 2023;
- the decrease in personnel related costs related to a $1.8 million decrease in stock-based compensation and the capitalization of certain inventory costs which were recorded as research and development personnel related costs prior to the EUA of PEMGARDA; and
- the decrease in external discovery-related and other costs resulted from a $1.9 million decrease in contract manufacturing costs and $0.9 million decrease in other nonclinical expenses, partially offset by a $1.2 million increase in other external costs related to our pipeline candidates.

Acquired In-Process Research and Development ("IPR&D") Expenses

There was no IPR&D expense recognized during the three months ended September 30, 2024.

IPR&D expenses of $4.6 million for the three months ended September 30, 2023 consisted of $3.2 million incurred related to a milestone under the Adimab Assignment Agreement and $1.4 million incurred related to an option exercise fee, a drug discovery fee and an optimization completion fee under the Adimab Collaboration Agreement.

Selling, General and Administrative Expenses

(in thousands)	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Change
Personnel related (including stock-based compensation)	$ 4,932	$ 6,939	$ (2,007)
Professional and consultant fees	7,340	5,424	1,916
Other	683	523	160
Total selling, general and administrative expenses	$ 12,955	$ 12,886	$ 69

Selling, general and administrative expenses were $13.0 million for the three months ended September 30, 2024, compared to $12.9 million for the three months ended September 30, 2023. The $0.1 million increase in selling, general and administrative expenses was primarily due to the following:

- the decrease in personnel related costs was primarily due to decreases in headcount and stock-based compensation;
- the increase in professional and consultant fees was primarily due to a $3.7 million increase related to the commercialization of PEMGARDA, partially offset by a $1.4 million and $0.3 million decrease in professional service fees and director and officer insurance premiums, respectively; and

- other costs remained relatively consistent between periods.

Other Income

Other income was $1.6 million for the three months ended September 30, 2024, consisting primarily of interest earned on our invested cash balances.

Other income was $3.6 million for the three months ended September 30, 2023, consisting of $1.9 million of interest earned on our invested cash balances and $1.7 million of net accretion of discounts related to our marketable securities.

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

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023:

(in thousands)	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023	Change
Revenue:			
Product revenue, net	$ 11,564	$ —	$ 11,564
Total revenue	11,564	—	11,564
Operating costs and expenses:			
Cost of product revenue	894	—	894
Research and development	119,344	96,393	22,951
Acquired in-process research and development	—	5,575	(5,575)
Selling, general and administrative	48,973	34,038	14,935
Total operating costs and expenses	169,211	136,006	33,205
Loss from operations	(157,647)	(136,006)	(21,641)
Other income (expense):			
Other income (expense), net	6,165	11,017	(4,852)
Total other income (expense), net	6,165	11,017	(4,852)
Net loss	$ (151,482)	$ (124,989)	$ (26,493)

The following discussion presents the components of our expenses for the periods presented:

Product Revenue, Net

Product revenue, net was $11.6 million for the nine months ended September 30, 2024. There was no product revenue, net for the nine months ended September 30, 2023. The $11.6 million increase is the result of product sales following the launch of PEMGARDA in the second quarter of 2024.

Cost of Product Revenue

Cost of product revenue was $0.9 million for the nine months ended September 30, 2024. There was no cost of product revenue for the nine months ended September 30, 2023. The $0.9 million increase is the result of PEMGARDA product sales following launch and certain period costs.

We began capitalizing our inventory costs in March 2024, in connection with EUA from the FDA and based upon our expectation that these costs would be recoverable through commercialization of PEMGARDA. Prior to the capitalization of our inventory costs, such costs were recorded as research and development expenses in the period incurred. Had our pre-EUA manufacturing costs been capitalized, our reported margins would approach 80%.

Research and Development Expenses

(in thousands)	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023	Change
Direct, external research and development expenses by program:			
VYD222[(1)]	$ 27,936	$ 52,694	$ (24,758)
VYD2311[(2)]	64,175	—	64,175
Adintrevimab	475	3,363	(2,888)
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	14,403	20,978	(6,575)
External discovery-related and other costs	12,355	19,358	(7,003)
Total research and development expenses	$ 119,344	$ 96,393	$ 22,951

[(1)] In March 2023, we announced the nomination of VYD222 as a novel mAb therapeutic option for COVID-19.

[(2)] In March 2024, we announced the nomination of VYD2311 as a novel mAb therapeutic option for COVID-19.

Research and development expenses were $119.3 million for the nine months ended September 30, 2024, compared to $96.4 million for the nine months ended September 30, 2023. The $22.9 million increase in research and development expenses was primarily due to the following:

- the decrease in direct costs related to our VYD222 program resulted from $26.5 million in contract costs for commercial manufacturing and $0.5 million in nonclinical expenses, partially offset by increases of $1.8 million in contract research costs for our CANOPY clinical trial and $0.5 million in other external expenses;
- the increase in direct costs related to our VYD2311 program resulted from the nomination of our VYD2311 product candidate in the first quarter of 2024 and consisted primarily of contract manufacturing costs and nonclinical expenses;
- the decrease in direct costs related to our adintrevimab program of $2.9 million resulted from the nomination of our VYD222 product candidate in the first quarter of 2023;
- the decrease in personnel related costs related to capitalization of $4.0 million of certain inventory costs which were recorded as research and development costs prior to the EUA of PEMGARDA and a $2.6 million decrease primarily due to a reduction in headcount, including a $0.7 million decrease due to stock-based compensation; and
- the decrease in external discovery-related and other costs resulted from a $5.1 million decrease in contract manufacturing costs related to our pipeline candidates and a $2.7 million decrease in other nonclinical expenses, partially offset by a $0.6 million increase in other external costs and $0.2 million in clinical trial expenses.

Acquired In-Process Research and Development ("IPR&D") Expenses

There was no IPR&D expense recognized during the nine months ended September 30, 2024.

IPR&D expenses of $5.6 million for the nine months ended September 30, 2023 consisted of $3.6 million incurred related to milestones under the Adimab Assignment Agreement, $1.4 million incurred related to an option exercise fee, a drug discovery fee and an optimization completion fee under the Adimab Collaboration Agreement, and $0.6 million incurred related to license fees under the WuXi Biologics' Cell Line License Agreement.

Selling, General and Administrative Expenses

(in thousands)	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023	Change
Personnel related (including stock-based compensation)	$ 24,728	$ 18,690	$ 6,038
Professional and consultant fees	22,024	13,849	8,175
Other	2,221	1,499	722
Total selling, general and administrative expenses	$ 48,973	$ 34,038	$ 14,935

Selling, general and administrative expenses were $49.0 million for the nine months ended September 30, 2024, compared to $34.0 million for the nine months ended September 30, 2023. The $14.9 million increase in selling, general and administrative expenses was primarily due to the following:

- the increase in personnel related costs was primarily due to an increase in headcount-related costs, including an increase in stock-based compensation expense of $4.0 million that was primarily due to the accelerated vesting of a portion of the outstanding stock options granted to our former Chief Executive Officer, in accordance with the terms of his employment agreement; and
- the increase in professional and consultant fees and other costs of $8.2 million and 0.7 million, respectively, was primarily related to the commercialization of PEMGARDA.

Other Income

Other income was $6.2 million for the nine months ended September 30, 2024, consisting primarily of interest earned on our invested cash balances.

Other income was $11.0 million for the nine months ended September 30, 2023, consisting primarily of $4.6 million of interest earned on our invested cash balances and $6.4 million of net accretion of discounts related to our marketable securities.

Liquidity and Capital Resources

Sources of Liquidity

Through September 30, 2024, we have incurred significant operating losses and negative cash flows from operations. Although we received an EUA from the FDA for PEMGARDA in March 2024, we may continue to incur significant expenses and potential operating losses for the foreseeable future as we commercialize PEMGARDA and advance the development of our other product candidates. To date, we have financed our operations primarily with net proceeds of $464.7 million from sales of our preferred stock, with aggregate net proceeds from our IPO in August 2021 of $327.5 million, and with net proceeds of $39.3 million from sales of our common stock under the Sales Agreement (as defined below). After receiving EUA in March 2024, we have also funded our operations from sales of PEMGARDA.

In December 2023, we entered into a Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor"), pursuant to which we may, at our option, offer and sell shares of our common stock, with a sales value of up to $75.0 million, from time to time, through Cantor, acting as sales agent, in transactions deemed to be "at the market offerings", as defined in Rule 415 under the Securities Act of 1933, as amended. Cantor is entitled to a commission of 3% of the gross proceeds from any sales of such shares. In February 2024, we sold 9,000,000 shares of our common stock under the Sales Agreement at an average price of $4.50 per share for $39.3 million in net proceeds. As of September 30, 2024, $34.5 million remained available for sale under the Sales Agreement.

As of September 30, 2024, we had cash and cash equivalents of $106.9 million.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

(in thousands)	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Net cash used in operating activities	$ (132,881)	$ (113,924)
Net cash (used in) provided by investing activities	(145)	202,766
Net cash provided by financing activities	39,254	904
Net (decrease) increase in cash and cash equivalents	$ (93,772)	$ 89,746

Operating Activities

During the nine months ended September 30, 2024, operating activities used $132.9 million of cash, primarily due to our net loss of $151.5 million, partially offset by non-cash charges of $18.3 million and changes in our operating assets and liabilities of $0.3 million. The changes in our operating assets and liabilities primarily consisted of a $16.0 million increase in accrued expenses, a $15.3 million decrease in prepaid expenses, and a $9.7 million increase in accounts payable, partially offset by a $23.4 million increase in inventory, a $8.1 million increase in accounts receivables, a $7.3 million increase in other non-current assets, a $1.2 million decrease in operating lease liabilities and a $0.7 million decrease in other non-current liabilities. The increase in accrued expenses was primarily due to the timing of vendor invoicing and payments. The decrease in prepaid expenses and other current assets was primarily due to the utilization of WuXi Biologics manufacturing prepayments.

During the nine months ended September 30, 2023, operating activities used $113.9 million of cash, primarily due to our net loss of $125.0 million, partially offset by non-cash charges of $9.6 million and changes in our operating assets and liabilities of $1.5 million. The changes in our operating assets and liabilities primarily consisted of a $7.7 million increase in accounts payable and a $0.7 million increase in non-current liabilities, partially offset by a $5.5 million decrease in accrued expenses, a $1.2 million decrease in operating lease liabilities, and a $0.3 million increase in prepaid expenses and other current assets. The increase in accounts payable and decrease in accrued expenses was primarily due to the timing of vendor invoicing and payments.

Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2024 consisted of $0.1 million in purchases of property and equipment.

Net cash provided by investing activities during the nine months ended September 30, 2023 consisted of $294.6 million in maturities of marketable securities, offset by $91.2 million in purchases of marketable securities and $0.6 million in purchases of property and equipment.

Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2024 consisted of $39.3 million from the issuance of common stock under the Sales Agreement, $0.3 million from exercises of stock options, and $0.2 million from the issuance of common stock under the employee stock purchase plan, offset by $0.5 million in payments for offering costs related to the Sales Agreement.

Net cash provided by financing activities during the nine months ended September 30, 2023 consisted of $0.7 million from exercises of stock options and $0.2 million from the issuance of common stock under the employee stock purchase plan.

Funding Requirements

Our expenses could increase in connection with our ongoing activities, particularly as we advance the nonclinical and preclinical studies and the clinical trials of our product candidates, including any associated manufacturing activities, and commercialization efforts. Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including:

- the revenue received from sales of PEMGARDA and any other product candidates for which we receive future regulatory authorization or approval;
- the rate of progress in the development of our product candidates;
- the scope, progress, results and costs of discovery, nonclinical studies, preclinical development, laboratory testing and clinical trials for our product candidates and associated development programs;
- the extent to which we develop, in-license or acquire other product candidates, intellectual property and/or technologies;
- the scope, progress, results and costs of manufacturing and validation activities associated with our current product candidates with the development and manufacturing of our future product candidates as we advance them through preclinical and clinical development;
- the number and development requirements of product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- our headcount growth and associated costs as we expand our research and development capabilities and build and maintain a commercial infrastructure for product candidates for which we obtain regulatory authorization or approval;
- the timing and costs of securing sufficient manufacturing capacity for clinical and commercial supply of our product candidates, or the raw material components thereof;
- the costs and timing of commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive regulatory authorization or approval;
- the costs necessary to obtain regulatory authorizations or approvals, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where authorization or approval is obtained;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the continuation of our existing licensing and collaboration arrangements and entry into new collaborations and licensing arrangements, if at all;
- the need and ability to hire and retain additional research, clinical, development, scientific and manufacturing personnel;
- the costs we incur in maintaining business operations;
- the need to implement additional internal systems and infrastructure;
- the effect of competing technological, product and market developments;
- the costs of operating as a public company; and
- the impact of any business interruptions to our operations or to those of our third-party contractors resulting from any public health crisis.

Substantial Doubt about Ability to Continue as a Going Concern

In accordance with Accounting Standards Update 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), we are required to evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern from the issuance date of our consolidated financial statements.

Based on current operating plans and excluding any contribution from future revenues or external financing, we will not have sufficient cash and cash equivalents to fund our operating expenses and capital requirements beyond one year from the issuance of these consolidated financial statements, and therefore, we have concluded that there is substantial doubt about our ability to continue as a going concern. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

We expect to finance our operations through a combination of contribution from revenues, equity offerings, government or private-party grants, debt financings or other capital sources, such as collaborations with other companies, strategic alliances or licensing arrangements to support our continuing operations and pursue our growth strategy. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to secure additional funds through contribution from revenues, equity or debt financings or through other sources, when needed, we may be required to delay, limit, reduce or terminate our product development programs or any commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

Through September 30, 2024, we committed to noncancelable purchase obligations related to commercial drug substance and drug product manufacturing under the Commercial Manufacturing Services Agreement with WuXi Biologics, which was entered into in December 2020, amended and restated in August 2021 and further amended and restated in September 2023 (as amended and restated, the "Commercial Manufacturing Agreement"). As of September 30, 2024, the total remaining contractually binding commercial drug substance and drug product purchase obligations due to WuXi Biologics was $38.3 million, which is expected to be paid in 2024 and 2025. As of September 30, 2024, $36.5 million related to the contractually binding commercial drug substance and drug product batches was included in accounts payable and accrued expenses, which is expected to be paid in 2024. Through September 30, 2024, we committed to noncancelable purchase obligations of $17.0 million related to the procurement of materials to be used in future drug substance and drug product manufacturing under the Commercial Manufacturing Agreement, which is expected to be paid in 2024. As of September 30, 2024, $10.6 million related to the procurement of materials to be used in future drug substance and drug product manufacturing was included in accounts payable and accrued expenses, which is expected to be paid in 2024. For additional information, see Note 9 to our condensed consolidated financial statements appearing in this Quarterly Report on Form 10-Q. Other than the above noted transactions, during the three and nine months ended September 30, 2024, there were no material changes to our contractual obligations from those described in the 2023 Form 10-K.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. Our critical accounting policies and estimates are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates" in the 2023 Form 10-K. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected. There have been no significant changes to our critical accounting policies and estimates from those described in the 2023 Form 10-K.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations and cash flows is disclosed in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of our IPO. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.235 billion or we issue more than $1.0 billion of non-convertible debt in the previous three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- an exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation;
- exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Financial Officer (our principal executive officer and principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2024, our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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) that occurred during the period covered by this Quarterly Report on Form 10-Q 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.

On January 31, 2023, a securities class action lawsuit captioned Brill v. Invivyd, Inc., et. al., Case No. 1:23-CV-10254-LTS, was filed against us and certain of our former officers in the U.S. District Court for the District of Massachusetts. The complaint alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder on the basis of purportedly materially false and misleading statements and omissions concerning ADG20's effectiveness against the Omicron variant of COVID-19. The complaint sought, among other things, unspecified damages, attorneys' fees, expert fees, and other costs. The court appointed lead plaintiffs for the action on June 28, 2023. On August 23, 2023, the lead plaintiffs filed an amended complaint that made allegations similar to those in the original complaint and asserted the same claims against the same defendants as the original complaint. On October 19, 2023, the parties filed a joint stipulation to advise the court that the lead plaintiffs intended to seek leave to file a second amended complaint, and on November 22, 2023, the lead plaintiffs filed a second amended complaint that made allegations similar to those in the prior complaints and asserted the same claims against the same defendants as the prior complaints. On January 12, 2024, the defendants filed a motion to dismiss the second amended complaint in its entirety. The lead plaintiffs filed an opposition to the motion to dismiss on February 26, 2024, and the defendants filed a reply in further support of their motion to dismiss on March 27, 2024. The court heard oral arguments on the defendants' motion to dismiss on May 10, 2024. The court granted the defendants' motion to dismiss on September 18, 2024, dismissing the second amended complaint in its entirety, with prejudice and without leave to amend. The plaintiffs did not appeal the court's decision. As such, we have concluded that this matter is closed.

Item 1A. Risk Factors.

Information regarding risks and uncertainties related to our business appears in Part I, Item 1A. "Risk Factors" of the 2023 Form 10-K. As of the date of this Quarterly Report on Form 10-Q, there have been no material changes from the risk factors set forth in the 2023 Form 10-K, other than as described below.

Risks Related to the Commercialization of Our Product Candidates

Our commercial prospects may be harmed if academic or other third-party labs unrelated to Invivyd generate virologic activity data that creates doubt regarding the neutralization activity of pemivibart or any other of Invivyd's product candidates, even if such data is ultimately shown to be inconsistent with neutralization data generated through Invivyd's industrial-grade virology efforts.

From time to time, academic or other third-party labs unrelated to Invivyd may produce and run tests on their own molecules meant to resemble Invivyd molecules, such as pemivibart, or run tests on Invivyd molecules utilizing differing assays, and put neutralization findings of unknown quality into the public domain. In connection with the emergency use authorization ("EUA") for PEMGARDA™ (pemivibart), the U.S. Food and Drug Administration ("FDA") has acknowledged that neutralization findings from sources other than Invivyd's independent, contracted vendor may differ due to, among other reasons, assay differences or because the molecule tested by other labs differs from pemivibart in sequence. Nevertheless, publicly available neutralization data against emerging SARS-CoV-2 variants are reviewed by the FDA and may be factored into the totality of evidence when considering the potential for adequate neutralization activity of PEMGARDA to support continued emergency use authorization.

To the extent that virologic activity data in the public domain generated by academic or other third-party labs unrelated to Invivyd creates doubt regarding the neutralization activity of pemivibart or other Invivyd product candidates, it could adversely impact our regulatory authorization and market acceptance by healthcare providers ("HCPs") or patients, particularly if such publicly available neutralization findings are referenced by the FDA in relation to the regulatory authorization of any Invivyd product candidate, which would adversely affect our commercial prospects and ability to generate revenues, even if such data is preliminary, non-peer-reviewed, and/or generated with molecules that are not authentic Invivyd molecules, and even if such data is ultimately shown to be inconsistent with neutralization data generated through Invivyd's industrial-grade virology efforts.

For example, in October 2024, Invivyd withdrew formal revenue guidance for FY2024 following growth headwinds after the FDA updated the PEMGARDA Fact Sheet for HCPs ("Fact Sheet") in August 2024 to include a link to contested, non-peer-reviewed neutralization data of a non-pemivibart antibody generated by an academic lab, which indicated that PEMGARDA may have reduced susceptibility to certain SARS-CoV-2 variants, including KP.3.1.1. In September 2024, we announced that pseudovirus in vitro neutralization data generated by Invivyd's independent, contracted vendor as part of our industrial-grade virology efforts showed continued neutralizing activity of PEMGARDA against KP.3.1.1 and other SARS-CoV-2 variants tested, and later that month, the FDA re-issued an updated PEMGARDA Fact Sheet to provide accurate in vitro neutralization activity of PEMGARDA against dominant circulating variants, including KP.3.1.1. However, this series of events resulted in confusion in the HCP and vulnerable population communities about PEMGARDA and negatively impacted our net product revenue growth.

If academic or other third-party labs unrelated to Invivyd generate virologic activity data that creates doubt regarding the neutralization activity of pemivibart or any other of Invivyd's product candidates, our regulatory authorization and our commercial

prospects may be harmed, even if such data is ultimately shown to be inconsistent with neutralization data generated through Invivyd's industrial-grade virology efforts.

Risks Related to Our Dependence on Third Parties

We currently rely on third parties to conduct, supervise, analyze and monitor a significant portion of our nonclinical activities and clinical trials for our product candidates, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain or maintain regulatory authorization or approval or successfully commercialize product candidates, or such authorization or approval or commercialization may be delayed or impaired, and our business may be substantially harmed.

We have engaged contract research organizations ("CROs") and other third parties to conduct nonclinical activities and clinical trials for our product candidates, and to monitor and manage data. We expect to continue to rely on third parties such as clinical data management organizations, medical institutions and clinical investigators to conduct such activities and trials. We also rely on third parties for their research and discovery capabilities, including the nonclinical activity of assay development and virology testing of our product candidates. Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties on commercially reasonable terms, if at all. Switching or adding CROs or other third-party vendors requires management time and focus, and may involve substantial cost or result in delays that materially impact our ability to meet our desired program timelines for our product candidates. Though we intend to carefully manage our relationships with our CROs and other third-party vendors, there can be no assurance that we will not encounter challenges or delays in the future or that any such delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

In addition, any third parties conducting our nonclinical activities or our clinical trials, or monitoring and managing our data, will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the nonclinical, clinical or other data they generate or otherwise obtain is compromised or not timely made available to us or regulatory authorities, due to the failure to adhere to applicable protocols, regulatory requirements, contractual obligations or for other reasons, our preclinical studies or clinical trials may be extended, delayed or terminated, the strength and reliability of our data may be adversely impacted, which may impact our ability to obtain or maintain regulatory authorization or approval, or result in modification to the regulatory authorization or approval documents (e.g., EUA fact sheet, letter of authorization or prescribing information), and may impact our ability to successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates may be harmed, our costs could increase substantially and our ability to generate revenue could be impaired significantly. For example, following receipt of EUA from the FDA in March 2024 for PEMGARDA™ (pemivibart) for the pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and adolescent individuals (12 years of age and older weighing at least 40 kg), we were informed in mid-July 2024 by our third-party authentic virus neutralization assay ("AVNA") vendor that a possible contamination event may have impacted the AVNA potency value generated by such vendor for pemivibart against JN.1, which was the dominant circulating SARS-CoV-2 variant in the United States between January 2024 and April 2024. Along with the pseudotyped viral neutralization assay ("PVNA") potency value for pemivibart against JN.1, the original PEMGARDA Fact Sheet reflected the AVNA potency value for pemivibart against JN.1.We have been pursuing additional AVNA assay work with multiple third-party AVNA vendors to reassess the AVNA potency value for pemivibart against JN.1, while also working with our third-party PVNA vendor to continue to generate and provide the FDA with PVNA potency data against SARS-CoV-2 variants, as required by the PEMGARDA EUA. As a result of the possible contamination event at our third-party AVNA vendor that may have impacted the AVNA potency value for pemivibart against JN.1, the FDA made modifications to the PEMGARDA Fact Sheet, including, among other changes, removal of the AVNA potency value for pemivibart against JN.1 and incorporation of certain other available information for HCPs to consider when determining whether to prescribe PEMGARDA.

Our reliance on CROs and other third parties reduces our control over our nonclinical activities and clinical trials, but does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as current Good Clinical Practices ("cGCPs"), for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before authorizing or approving our product candidates. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with cGCP regulations. In addition, our clinical trials must be conducted with product produced under current Good Manufacturing Practices conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory authorization or approval process for our product candidates.

We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, such as ClinicalTrials.gov, within specified timeframes. This remains our obligation regardless of whether we have contracted any third party to assist and failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized, which may lead to the delay or denial of regulatory authorization or approval for our product candidates.

We also expect to rely on other third parties to label, package, store and distribute product supplies for our clinical trials. Any performance failure on the part of such third parties could delay clinical development or marketing approval or authorization of our product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue.

If our CROs or other third-party vendors do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain or maintain regulatory authorization or approval or successfully commercialize product candidates, or such authorization or approval or commercialization may be delayed or impaired, and our business may be substantially harmed.

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

Recent Sales of Unregistered Securities; Use of Proceeds

We did not issue any unregistered equity securities during the three months ended September 30, 2024.

Purchases of Equity Securities by the Issuer

We did not purchase any of our equity securities during the three months ended September 30, 2024.

Item 5. Other Information.

Trading Plans

During the three months ended September 30, 2024, none of our directors or officers adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408 of Regulation S-K.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on August 10, 2021).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on September 13, 2022).
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on May 25, 2023).
3.4	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on September 13, 2022).
3.5	Amendment No. 1 to the Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on May 25, 2023).
3.6	Delaware Certificate of Change of Registered Agent (incorporated by reference to Exhibit 3.3 of the Company's Registration Statement on Form S-3 (File No. 333-267643), filed with the Securities and Exchange Commission on September 28, 2022).
31.1*	Certification of Principal Executive Officer and 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.
32.1^	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Filed herewith.

^ Furnished herewith and not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

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.

INVIVYD, INC.

Date: November 14, 2024

By: /s/ William Duke, Jr.

William Duke, Jr.
Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION 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

I, William Duke, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Invivyd, 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my 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. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 14, 2024

By: /s/ William Duke, Jr.

William Duke, Jr.
Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal 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 of Invivyd, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: November 14, 2024

By: /s/ William Duke, Jr.

William Duke, Jr.
Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.