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

FORM 10-Q

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

For the quarterly period ended June 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: 001-33221

HERON THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-2875566**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4242 Campus Point Court, Suite 200 San Diego, CA	**92121**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(858) 251-4400**

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, par value $0.01 per share	HRTX	The Nasdaq Capital 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 ☑

The number of shares of the registrant's common stock, par value $0.01 per share, outstanding as of August 1, 2024 was 151,668,017.

HERON THERAPEUTICS, INC.

FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2024

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

HERON THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(In thousands)

	June 30, 2024 (Unaudited)	December 31, 2023 (See Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,386	$ 28,677
Short-term investments	48,961	51,732
Accounts receivable, net	73,708	60,137
Inventory	42,864	42,110
Prepaid expenses and other current assets	7,249	6,118
Total current assets	191,168	188,774
Property and equipment, net	15,900	20,166
Right-of-use lease assets	4,138	5,438
Other assets	6,930	8,128
Total assets	$ 218,136	$ 222,506
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 10,226	$ 3,240
Accrued clinical and manufacturing liabilities	17,554	22,291
Accrued payroll and employee liabilities	7,085	9,224
Other accrued liabilities	42,258	41,855
Current lease liabilities	3,194	3,075
Total current liabilities	80,317	79,685
Non-current lease liabilities	1,289	2,800
Non-current notes payable, net	24,634	24,263
Non-current convertible notes payable, net	149,595	149,490
Other non-current liabilities	241	241
Total liabilities	256,076	256,479
Stockholders' deficit:		
Common stock	1,516	1,503
Additional paid-in capital	1,878,961	1,870,525
Accumulated other comprehensive (loss) income	(8)	13
Accumulated deficit	(1,918,409)	(1,906,014)
Total stockholders' deficit	(37,940)	(33,973)
Total liabilities and stockholders' deficit	$ 218,136	$ 222,506

See accompanying notes.

HERON THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues:				
Net product sales	$ 36,024	$ 31,762	$ 70,694	$ 61,377
Cost of product sales	10,518	20,158	18,962	37,012
Gross Profit	25,506	11,604	51,732	24,365
Operating expenses:				
Research and development	4,432	13,210	9,040	22,046
General and administrative	13,905	19,592	28,879	35,426
Sales and marketing	13,614	21,205	25,056	42,359
Total operating expenses	31,951	54,007	62,975	99,831
Loss from operations	(6,445)	(42,403)	(11,243)	(75,466)
Other (expense) income, net	(2,790)	344	(1,152)	639
Net loss	(9,235)	(42,059)	(12,395)	(74,827)
Other comprehensive loss:				
Unrealized (losses) gains on short-term investments	(2)	(15)	(21)	13
Comprehensive loss	$ (9,237)	$ (42,074)	$ (12,416)	$ (74,814)
Basic and diluted net loss per common share	$ (0.06)	$ (0.35)	$ (0.08)	$ (0.63)
Weighted average common shares outstanding, basic and diluted	152,305	119,719	151,900	119,484

See accompanying notes.

HERON THERAPEUTICS, INC.

Condensed Consolidated Statements of Stockholders' Deficit
(Unaudited)
(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
Balance as of December 31, 2023	150,285	$ 1,503	$ 1,870,525	$ 13	$ (1,906,014)	$ (33,973)
Issuance of common stock under equity incentive plan	93	1	10	—	—	11
Stock-based compensation expense	—	—	3,375	—	—	3,375
Net loss	—	—	—	—	(3,160)	(3,160)
Net unrealized loss on short-term investments	—	—	—	(19)	—	(19)
Comprehensive loss						(3,179)
Balance as of March 31, 2024 (unaudited)	150,378	1,504	1,873,910	(6)	(1,909,174)	(33,766)
Issuance of common stock under equity incentive plan	872	9	309	—	—	318
Issuance of common stock under the employee stock purchase plan	328	3	172	—	—	175
Stock-based compensation expense	—	—	4,570	—	—	4,570
Net loss	—	—	—	—	(9,235)	(9,235)
Net unrealized loss on short-term investments	—	—	—	(2)	—	(2)
Comprehensive loss						(9,237)
Balance as of June 30, 2024 (unaudited)	151,578	$ 1,516	$ 1,878,961	$ (8)	$ (1,918,409)	$ (37,940)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance as of December 31, 2022	119,155	$ 1,191	$ 1,807,855	$ (19)	$ (1,795,455)	$ 13,572
Issuance of common stock under equity incentive plan	125	2	(210)	—	—	(208)
Stock-based compensation expense	—	—	7,947	—	—	7,947
Net loss	—	—	—	—	(32,768)	(32,768)
Net unrealized gain on short-term investments	—	—	—	28	—	28
Comprehensive loss						(32,740)
Balance as of March 31, 2023 (unaudited)	119,280	1,193	1,815,592	9	(1,828,223)	(11,429)
Issuance of common stock under equity incentive plan	330	3	(388)	—	—	(385)
Issuance of common stock under the employee stock purchase plan	346	3	701	—	—	704
Stock-based compensation expense	—	—	13,900	—	—	13,900
Net loss	—	—	—	—	(42,059)	(42,059)
Net unrealized loss on short-term investments	—	—	—	(15)	—	(15)
Comprehensive loss						(42,074)
Balance as of June 30, 2023 (unaudited)	119,956	$ 1,199	$ 1,829,805	$ (6)	$ (1,870,282)	$ (39,284)

See accompanying notes.

HERON THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Six Months Ended June 30,	
	2024	**2023**
Operating activities:		
Net loss	$ (12,395)	$ (74,827)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	7,945	21,847
Depreciation and amortization	1,330	1,457
Amortization of debt discount	180	103
Amortization of debt issuance costs	104	—
Accretion of discount on short-term investments	(1,211)	(835)
Impairment of property and equipment	3,441	309
Loss on disposal of property and equipment	—	23
Change in operating assets and liabilities:		
Accounts receivable	(13,571)	(24,644)
Inventory	(754)	9,950
Prepaid expenses and other assets	67	10,369
Accounts payable	6,986	(1,268)
Accrued clinical and manufacturing liabilities	(4,605)	(4,587)
Accrued payroll and employee liabilities	(2,139)	(3,560)
Other accrued and other non-current liabilities	502	13,598
Net cash used in operating activities	(14,120)	(52,065)
Investing activities:		
Purchases of short-term investments	(65,100)	(28,381)
Maturities and sales of short-term investments	69,063	78,935
Purchases of property and equipment	(637)	(502)
Net cash provided by investing activities	3,326	50,052
Financing activities:		
Receipts (Payments) for stock issued under the equity incentive plan	328	(593)
Proceeds from purchases under the employee stock purchase plan	175	704
Net cash provided by financing activities	503	111
Net decrease in cash and cash equivalents	(10,291)	(1,902)
Cash and cash equivalents at beginning of year	28,677	15,364
Cash and cash equivalents at end of period	$ 18,386	$ 13,462
Supplemental disclosure of cash flow information:		
Interest paid	$ 2,426	$ 1,125

See accompanying notes.

In this Quarterly Report on Form 10-Q, all references to "Heron," the "Company," "we," "us," "our" and similar terms refer to Heron Therapeutics, Inc. and its wholly owned subsidiary, Heron Therapeutics B.V. Heron Therapeutics®, the Heron logo, ZYNRELEF®, APONVIE®, CINVANTI®, SUSTOL®, and Biochronomer® are our trademarks. All other trademarks appearing or incorporated by reference into this Quarterly Report on Form 10-Q are the property of their respective owners.

1. Business

We are a commercial-stage biotechnology company focused on improving the lives of patients by developing and commercializing therapeutic innovations that improve medical care. Our advanced science, patented technologies, and innovative approach to drug discovery and development have allowed us to create and commercialize a portfolio of products that aim to advance the standard of care for acute care and oncology patients.

ZYNRELEF (bupivacaine and meloxicam) extended-release solution ("ZYNRELEF") is approved in the United States ("U.S.") for the management of postoperative pain. APONVIE (aprepitant) injectable emulsion ("APONVIE") is approved in the U.S. for the prevention of postoperative nausea and vomiting. CINVANTI (aprepitant) injectable emulsion ("CINVANTI") and SUSTOL (granisetron) extended-release injection ("SUSTOL") are both approved in the U.S. for the prevention of chemotherapy-induced nausea and vomiting.

As of June 30, 2024, we had cash, cash equivalents and short-term investments of $67.3 million. Based on our current operating plan and projections, management believes that the Company's cash, cash equivalents and short-term investments will be sufficient to meet the Company's anticipated cash requirements for a period of at least one year from the date this Quarterly Report on Form 10-Q is filed with the U.S. Securities and Exchange Commission ("SEC").

2. Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and the requirements of the SEC for interim reporting. Accordingly, since they are interim statements, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2024 are not necessarily indicative of the results that may be expected for other quarters or the year ending December 31, 2024. The condensed consolidated balance sheet as of December 31, 2023 has been derived from the audited financial statements as of that date. For more complete financial information, these condensed consolidated financial statements and the notes thereto should be read in conjunction with the audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the SEC on March 12, 2024.

Reclassification of Certain Expenses

The condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2023 reflect reclassification of certain expenses from research and development to general and administrative expenses to align with the Company's presentation for the three and six months ended June 30, 2024 as a result of the restructuring implemented in 2023 and the realignment of the Company's departments. This presentation results in no change to total operating expenses, loss from operations or net loss and no pro forma financial information is necessary.

3. Accounting Policies

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of Heron Therapeutics, Inc. and its wholly owned subsidiary, Heron Therapeutics B.V., which was organized in the Netherlands in March 2015. Heron Therapeutics B.V. has no operations and no material assets or liabilities, and there have been no significant transactions related to Heron Therapeutics B.V. since its inception.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes to the financial statements. Our significant accounting policies that involve significant judgment and estimates include revenue recognition, investments, inventory and the related reserves, accrued clinical liabilities, income taxes and stock-based compensation. Actual results could differ materially from those estimates.

Cash, Cash Equivalents and Short-Term Investments

Cash and cash equivalents consist of cash and highly liquid investments with contractual maturities of three months or less from the original purchase date.

Short-term investments consist of securities with contractual maturities of greater than three months from the original purchase date. Securities with contractual maturities greater than one year are classified as short-term investments on the condensed consolidated balance sheets, as we have the ability, if necessary, to liquidate these securities to meet our liquidity needs in the next 12 months. We have classified our short-term investments as available-for-sale securities in the accompanying condensed consolidated financial statements. Available-for-sale securities are stated at fair market value, with net changes in unrealized gains and losses reported in other comprehensive income (loss) and realized gains and losses included in other income (expense), net. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income within other income (expense), net.

Our bank and investment accounts have been placed under a control agreement in accordance with our working capital facility agreement (see Note 8).

Concentration of Credit Risk

Cash, cash equivalents and short-term investments are financial instruments that potentially subject us to concentrations of credit risk. We deposit our cash in financial institutions. At times, such deposits may be in excess of insured limits. We have not experienced any losses in such accounts and believe we are not exposed to significant risk with respect to our cash, cash equivalents and short-term investments, however, any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations and cash flows.

We may also invest our excess cash in money market funds, U.S. government and agencies, corporate debt securities and commercial paper. We have established guidelines relative to our diversification of our cash investments and their maturities in an effort to maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

ZYNRELEF, APONVIE, CINVANTI and SUSTOL (collectively, our “Products”) are distributed in the U.S. through a limited number of specialty distributors and full line wholesalers (collectively, “Customers”) that resell to healthcare providers and hospitals, the end users of our Products.

The following table includes the percentage of net product sales and accounts receivable balances for our three major Customers, each of which comprised 10% or more of our product sales:

	Net Product Sales		Accounts Receivable
	Three Months Ended June 30, 2024	Six Months Ended June 30, 2024	As of June 30, 2024
Customer A[(1)]	46.0%	45.1%	45.7%
Customer B	34.6%	36.2%	35.1%
Customer C	18.3%	17.7%	18.8%
Total	98.9%	99.0%	99.6%

(1) Includes net product sales and accounts receivable balances for a subsidiary of Customer A that were reported separately in the Company's Form 10-Q for the three months ended March 31, 2024, filed with the SEC on May 7, 2024.

Accounts Receivable, Net

Accounts receivable are recorded at the invoice amount, net of an allowance for credit losses. The allowance for credit losses reflects accounts receivable balances that are believed to be uncollectible. As of June 30, 2024, we do not have an allowance for credit losses. In estimating the allowance for credit losses, we consider (1) our historical experience with collections and write-offs; (2) the credit quality of our Customers and any recent or anticipated changes thereto; (3) the outstanding balances and past due amounts from our Customers; and (4) reasonable and supportable forecast of economic conditions expected to exist throughout the contractual term of the receivable.

Inventory

Inventory is stated at the lower of cost or estimated net realizable value on a first-in, first-out, or FIFO, basis. We periodically analyze our inventory levels and write down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and inventory quantities that are in excess of expected sales requirements as cost of product sales. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required, which would be recorded as cost of product sales.

Property and Equipment, Net

Property and equipment is stated at cost less accumulated depreciation and amortization. Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets (generally 5 years). Leasehold improvements are stated at cost and amortized on a straight-line basis over the shorter of the estimated useful life of the asset or the lease term. During the three months ended June 30, 2024 we incurred a loss on the write-off of property and equipment of $3.1 million, of which $2.5 million relates to a project for which we had a one-time settlement gain contingency related to a legal dispute, during the three months ended March 31, 2024. This loss was recorded to other (expense) income, net. The remaining loss was recorded to operating expenses.

Leases

We determine if an arrangement is a lease or contains lease components at inception. Operating leases with an initial term greater than 12 months are recorded as lease liabilities with corresponding right-of-use ("ROU") lease assets on the condensed consolidated balance sheets. ROU lease assets represent our right to use the underlying assets over the lease term, and lease liabilities represent the present value of our obligation to make lease payments arising from the lease. Lease liabilities are recognized at the lease commencement based on the present value of lease payments over the lease term. As most of our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. We use the implicit rate when readily determinable. The ROU lease assets equal the lease liabilities, less unamortized lease incentives, unamortized initial direct costs and the cumulative difference between rent expense and amounts paid under the lease. The lease term includes any option to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense is recognized on a straight-line basis over the lease term. We have elected the practical expedient to not separate lease and non-lease components.

Revenue Recognition

Revenue is recognized in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customer*s ("Topic 606"). Topic 606 is based on the principle that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

Product Sales

Our Products are distributed in the U.S. through a limited number of Customers that resell to healthcare providers and hospitals, the end users of our Products.

Revenue is recognized in an amount that reflects the consideration we expect to receive in exchange for our Products. To determine revenue recognition for contracts with Customers within the scope of Topic 606, we perform the following five steps: (i) identify the contract(s) with a Customer; (ii) identify the performance obligations of the contract(s); (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract(s); and (v) recognize revenue when (or as) we satisfy the performance obligations. We recognize revenue from Product sales when there is a transfer of control of the Product to our Customers. We typically determine transfer of control based on when the Product is delivered, and title passes to our Customers.

Product Sales Allowances

We recognize product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. Such variable consideration includes estimates that take into consideration the terms of our agreements with Customers, historical product returns, rebates or discounts taken, the shelf life of the product and specific known market events, such as competitive pricing and new product introductions. If actual future results vary from our estimates, we may need to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. Our product sales allowances include:

- Product Returns—We allow the majority of our Customers to return product for credit beginning three months prior to the product expiration date and up to 12 months after the product expiration date. As such, there may be a significant period of time between the time the product is shipped and the time the credit is issued on returned product.
- Distributor Fees—We pay distribution service fees to our Customers based on a contractually fixed percentage of the wholesale acquisition costs and fees for data. These fees are paid no later than two months after the quarter in which product was shipped.
- Group Purchasing Organization ("GPO") Discounts and Rebates—We offer cash discounts to GPO members. These discounts are taken when the GPO members purchase product from our Customers, who then charge back to us the discount amount. Additionally, we offer volume and contract-tier rebates to GPO members. Rebates are based on actual purchase levels during the quarterly rebate purchase period.
- GPO Administrative Fees—We pay administrative fees to GPOs for services and access to data. These fees are based on contracted terms and are paid after the quarter in which the product was purchased by the GPO's members.
- Medicaid Rebates—We participate in Medicaid rebate programs, which provide assistance to certain low-income patients based on each individual state's guidelines regarding eligibility and services. Under the Medicaid rebate programs, we pay a rebate to each participating state, generally within six months after the quarter in which the product was sold.
- Prompt Pay Discounts—We may provide discounts on product sales to our Customers for prompt payment based on contractual terms.

We believe our estimated allowance for product returns and GPO discounts requires a high degree of judgment and is subject to change based on our experience and certain quantitative and qualitative factors. We believe our estimated allowances for distributor fees, GPO rebates and administrative fees, Medicaid rebates and prompt pay discounts do not require a high degree of judgment because the amounts are settled within a relatively short period of time.

Our product sales allowances and related accruals are evaluated each reporting period and adjusted when trends or significant events indicate that a change in estimate is appropriate. Changes in product sales allowance estimates could materially affect our results of operations and financial position.

The following table provides disaggregated net product sales (in thousands):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
CINVANTI net product sales	$ 24,927	$ 24,474	$ 50,544	$ 47,329
SUSTOL net product sales	4,246	2,836	7,860	5,819
ZYNRELEF net product sales	5,831	4,128	10,844	7,661
APONVIE net product sales	1,020	324	1,446	568
Total net product sales	$ 36,024	$ 31,762	$ 70,694	$ 61,377

The following table provides a summary of activity with respect to our product returns, distributor fees and discounts, rebates and administrative fees, which are included in other accrued liabilities on the condensed consolidated balance sheets (in thousands):

	Product Returns	Distributor Fees	Discounts, Rebates and Administrative Fees	Total
Balance at December 31, 2023	$ 4,776	$ 4,419	$ 27,334	$ 36,529
Provision	(1,216)	14,212	101,867	114,863
Payments/credits	(517)	(12,969)	(100,890)	(114,376)
Balance at June 30, 2024	$ 3,043	$ 5,662	$ 28,311	$ 37,016

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net changes in unrealized gains and losses on available-for-sale securities are included in other comprehensive income (loss) and represent the difference between our net loss and comprehensive loss for all periods presented.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, including pre-funded warrants to purchase shares of common stock. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock and common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, stock options, restricted stock units, warrants and shares of common stock underlying convertible notes are considered to be common stock equivalents and are included in the calculation of diluted net loss per share only when their effect is dilutive.

Because we have incurred a net loss for all periods presented in the unaudited condensed consolidated statements of operations and comprehensive loss, the following common stock equivalents were not included in the computation of net loss per share because their effect would be anti-dilutive (in thousands):

	June 30,	
	2024	2023
Stock options outstanding	27,445	28,778
Restricted stock units outstanding	1,642	2,732
Warrants outstanding	298	8,548
Shares of common stock underlying convertible notes outstanding	9,819	9,819

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that we adopt as of the specified effective date. We have evaluated recently issued accounting pronouncements and do not believe any will have a material impact on our condensed consolidated financial statements or related financial statement disclosures.

In December 2023, the FASB issued Accounting Standards Update ("ASU") No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), to enhance income tax reporting disclosures and require disclosure of

specific categories in the tabular rate reconciliation. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, on a prospective basis. Early adoption and retrospective application are permitted. We are currently evaluating the impact on our disclosures.

4. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) 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. The FASB ASC Topic 820, *Fair Value Measurements and Disclosures*, establishes a fair value hierarchy which prioritizes the inputs used in measuring fair value as follows:

- Level 1—Observable inputs such as quoted prices in active markets for identical assets or liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

We measure cash, cash equivalents and short-term investments at fair value on a recurring basis. The fair values of such assets were as follows (in thousands):

		Fair Value Measurements at Reporting Date Using		
	Balance at June 30, 2024	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and money market funds	$ 14,210	$ 14,210	$ —	$ —
U.S. Treasury bills and government agency obligations	31,634	31,634	—	—
U.S. corporate debt securities	11,202	—	11,202	—
Foreign corporate debt securities	10,301	—	10,301	—
Total	$ 67,347	$ 45,844	$ 21,503	$ —

		Fair Value Measurements at Reporting Date Using		
	Balance at December 31, 2023	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and money market funds	$ 23,441	$ 23,441	$ —	$ —
U.S. Treasury bills and government agency obligations	31,636	31,636	—	—
U.S. corporate debt securities	16,889	—	16,889	—
Foreign corporate debt securities	5,460	—	5,460	—
U.S. commercial paper	1,990	—	1,990	—
Foreign commercial paper	993	—	993	—
Total	$ 80,409	$ 55,077	$ 25,332	$ —

We have not transferred any investment securities between the three levels of the fair value hierarchy for the three and six months ended June 30, 2024 or 2023.

As of June 30, 2024, cash equivalents included $4.2 million of available-for-sale securities with contractual maturities of three months or less and short-term investments included $19.1 million of available-for-sale securities with contractual maturities of three months to one year. As of December 31, 2023, cash equivalents included $5.3 million of available-for-sale securities with contractual maturities of three months or less and short-term investments included $51.7 million of available-for-sale securities with contractual maturities of three months to one year. The money market funds as of June 30, 2024 and December 31, 2023 are included in cash and cash equivalents on the condensed consolidated balance sheets.

A company may elect to use fair value to measure accounts receivable, available-for-sale securities, accounts payable, guarantees and issued debt, among others. If the use of fair value is elected, any upfront costs and fees related to the item such as debt issuance costs must be recognized in earnings and cannot be deferred. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. Unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings and any changes in fair value are recognized in earnings. We have elected to not apply the fair value option to our financial assets and liabilities.

Financial instruments, including cash, cash equivalents, receivables, inventory, prepaid expenses, other current assets, accounts payable and accrued expenses are carried at cost, which is considered to be representative of their respective fair values because of the short-term maturity of these instruments. Short-term available-for-sale investments are carried at fair value. Our notes payable and convertible notes payable outstanding at June 30, 2024 and December 31, 2023 do not have a readily available ascertainable market value; however, their carrying value, which is measured at carrying value less unamortized debt issuance costs and debt discounts, is considered to approximate their fair value.

5. Short-Term Investments

The following is a summary of our short-term investments (in thousands):

	June 30, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury bills and government agency obligations	$ 30,151	$ 1	$ (3)	$ 30,149
U.S. corporate debt securities	8,513	—	(2)	8,511
Foreign corporate debt securities	10,305	—	(4)	10,301
Total	$ 48,969	$ 1	$ (9)	$ 48,961

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury bills and government agency obligations	$ 31,625	$ 11	$ —	$ 31,636
U.S. corporate debt securities	11,652	1	—	11,653
Foreign corporate debt securities	5,459	1	—	5,460
U.S. commercial paper	1,991	—	(1)	1,990
Foreign commercial paper	993	—	—	993
Total	$ 51,720	$ 13	$ (1)	$ 51,732

The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. We regularly monitor and evaluate the realizable value of our marketable securities. We did not recognize any impairment losses during the three and six months ended June 30, 2024 and 2023.

Unrealized gains and losses associated with our investments are reported in accumulated other comprehensive income (loss). Realized gains and losses associated with our investments, if any, are reported in the statements of operations and comprehensive loss. We did not recognize any realized gains or losses during the three and six months ended June 30, 2024 and 2023.

6. Inventory

Inventory consists of the following (in thousands):

	June 30, 2024	December 31, 2023
Raw materials	$ 19,594	$ 17,643
Work in process	16,051	14,550
Finished goods	7,219	9,917
Total inventory	$ 42,864	$ 42,110

As of June 30, 2024, total inventory included $28.9 million related to CINVANTI, $11.0 million related to ZYNRELEF, $2.9 million related to SUSTOL and $0.1 million related to APONVIE. As of December 31, 2023, total inventory included $26.4 million related to CINVANTI, $11.2 million related to ZYNRELEF, $4.1 million related to SUSTOL and $0.4 million for APONVIE. For the three and six months ended June 30, 2024, cost of product sales included charges of $1.6 million relating to reserves and write-offs of inventory. For the three and six months ended June 30, 2023, cost of product sales included charges of $7.5 million and $12.8 million, respectively, relating to the write-off of inventory.

7. Leases

As of June 30, 2024, we had an operating lease for 52,148 square feet of laboratory and office space in San Diego, California, with a lease term that expires on December 31, 2025. In October 2021, we entered into a sublease agreement to sublet 23,873 square feet of laboratory and office space. The space was delivered to the subtenant in March 2022. As a result of the sublease agreement, our one five-year option to renew this lease on expiration applies only with respect to our remaining 28,275 square feet of laboratory and office space.

We also have an operating lease through which we sublease 5,840 square feet of office space in Cary, North Carolina, with a lease term that expires on April 30, 2025.

During the three and six months ended June 30, 2024, we recognized $0.7 million and $1.5 million of operating lease expense, respectively. During the three and six months ended June 30, 2024, we paid $0.8 million and $1.6 million, respectively, for our operating leases.

During the three and six months ended June 30, 2023, we recognized $0.7 million and $1.4 million of operating lease expense, respectively. During the three and six months ended June 30, 2023, we paid $1.0 million and $1.7 million, respectively, for our operating leases.

Annual future minimum lease payments as of June 30, 2024 are as follows (in thousands):

2024	$ 1,578
2025	3,138
Total future minimum lease payments	$ 4,716
Less: discount	(233)
Total lease liabilities	**$ 4,483**

8. Long-Term Debt and Convertible Notes

Working Capital Facility Agreement

On August 9, 2023, we entered into a working capital facility agreement (the "Loan Agreement") with Hercules Capital, Inc., as administrative agent and collateral agent, and the lenders party thereto (the "Lenders"). The Loan Agreement provides an aggregate principal amount of up to $50.0 million with tranched availability as follows: $25.0 million at closing ("tranche 1A"), $5.0 million available through December 15, 2024 ("tranche 1B"), and $20.0 million available from the earlier of: (1) the full draw of tranche 1B and (2) the expiration of tranche 1B, and available through December 15, 2025 ("tranche 1C"), and in the case of tranches 1B and 1C, subject to certain customary conditions to draw down.

The Loan Agreement has a term of four years, with a springing maturity date that is 91 days prior to the stated maturity of our Notes (as defined below) (if still outstanding at such time). The loans thereunder do not have any scheduled amortization payments and accrue interest at a floating rate equal to, 9.95% per annum, payable in cash on a monthly basis and upon maturity or payoff. In addition, under the terms of the Loan Agreement, the loans also accrue paid-in-kind interest at a fixed-rate of 1.5% per annum which is due upon maturity or payoff.

In addition, in connection with the tranche 1A funding, we issued warrants to the Lenders to purchase up to 297,619 shares of our common stock at an exercise price of $1.68 per share (the "Lender Warrants"). The Lender Warrants are equal to 2.00% of the principal amount of tranche 1A loans funded by the Lenders (the "Warrant Coverage"). The Loan Agreement also requires that we issue additional warrants to the Lenders at the time of each draw down of tranches 1B and 1C with the same Warrant Coverage. Each Lender Warrant is exercisable for seven years from the date of issuance.

The Loan Agreement contains a minimum cash covenant, beginning on the closing date, requiring us to hold cash of no less than $8.5 million, if our market capitalization is less than $400.0 million. The Loan Agreement also contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness, and dividends and other distributions, subject to certain exceptions. We were in compliance with all covenants of the Loan Agreement as of June 30, 2024.

The Loan Agreement was accounted for in accordance with ASC Topic 470, Debt, ASC Topic 480, Distinguishing Liabilities from Equity, and ASC Topic 815, Derivatives and Hedging. The initial tranche 1A funding of $25.0 million and the Lender Warrants are accounted for as freestanding debt and equity financial instruments, respectively, as they are legally detachable and separately exercisable. The additional borrowings available under the Loan Agreement plus the additional warrants to purchase shares of our common stock, which would be issued concurrently, are accounted for as a single freestanding financial instrument that are not assets or obligations of ours; this financial instrument meets the loan commitment derivative scope exception and will be accounted for when and if we borrow additional tranches in the future. The initial funding of $25.0 million was recorded as a liability on the condensed consolidated balance sheets.

In connection with the Loan Agreement, we recognized the initial Lender Warrants at their relative fair value of $0.4 million, and we incurred debt issuance costs of $0.6 million, both of which were recorded as debt discounts. The debt discounts and the end of term fee, of $0.8 million, are being amortized and accreted into interest expense using the effective interest rate method over the term of the Loan Agreement, resulting in an effective interest rate of 14.5%. For the three and six months ended June 30, 2024, interest expense related to the Loan Agreement was $0.9 million and $1.8 million, respectively, which included $0.7 million and $1.3 million, respectively, related to the stated interest rate, $0.1 million and $0.2 million, respectively, related to paid-in-kind interest, and $0.2 million and $0.3 million, respectively, related to the amortization of the debt discounts. As of June 30, 2024, the carrying value of tranche 1A was $24.6 million, which is comprised of the $25.0 million principal amount outstanding, $0.3 million of accumulated paid-in-kind interest, less debt discounts of $0.7 million. The end of term fee accreted as of June 30, 2024 of $0.2 million is recorded in other accrued liabilities on the condensed consolidated balance sheets.

Senior Unsecured Convertible Notes

In May 2021, we entered into a note purchase agreement with funds affiliated with Baker Bros. Advisors LP for a private placement of $150.0 million in Senior Unsecured Convertible Notes (the "Notes"). We received a total of $149.0 million, net of issuance costs, from the issuance of the Notes.

The Notes were issued at par. The Notes bear interest at a rate of 1.5% per annum, payable in cash semi-annually in arrears on June 15 and December 15 of each year, beginning on December 15, 2021. The Notes mature on May 26, 2026, unless earlier converted, redeemed or repurchased.

The Notes are subject to redemption at our option, between May 24, 2024 and May 24, 2025, but only if the last reported sale price per share of our common stock exceeds 250% of the conversion price for a specified period of time, or will be subject to redemption at our option on or after May 24, 2025 if the last reported sale price per share of our common stock exceeds 200% of the conversion price for a specified period of time. The redemption price will be equal to the principal amount of the Notes to be redeemed, plus accrued and unpaid interest.

Upon conversion, we will settle the Notes in shares of our common stock. The initial conversion rate for the Notes is 65.4620 shares per $1,000 principal amount of the Notes (equivalent to an initial conversion price of $15.276 per share of common stock).

If a holder of the Notes converts upon a make-whole fundamental change or company redemption, the holder may be eligible to receive a make-whole premium through an increase to the conversion rate.

In May 2021, we filed a registration statement with the SEC to register for resale 12.4 million shares of our common stock underlying the Notes, including the maximum number of shares of common stock issuable under the make-whole premium.

The Notes were accounted for in accordance with ASC Subtopic 470-20, Debt with Conversion and Other Options ("ASC 470-20"), and ASC Subtopic 815-40, Contracts in Entity's Own Equity ("ASC 815-40"). Under ASC 815-40, to qualify for equity classification (or non-bifurcation, if embedded), the instrument (or embedded feature) must be both (1) indexed to the issuer's stock and (2) meet the requirements of the equity classification guidance. Based upon our analysis, it was determined that the Notes do contain embedded features indexed to our common stock, but do not meet the requirements for bifurcation, and therefore do not need to be separately accounted for as an equity component. Since the embedded conversion feature meets the equity scope exception from derivative accounting, and, also since the embedded conversion option does not need to be separately accounted for as an equity component under ASC 470-20, the proceeds received from the issuance of the Notes were recorded as a liability on the condensed consolidated balance sheets.

We incurred issuance costs related to the Notes of $1.0 million, which we recorded as debt issuance costs and are included as a reduction to the Notes on the condensed consolidated balance sheets. The debt issuance costs are being amortized to interest expense using the effective interest rate method over the term of the Notes, resulting in an effective interest rate of 1.6%. For the three and six months ended June 30, 2024, interest expense related to the Notes was $0.5 million and $1.1 million, respectively, which included $0.4 million and $1.0 million, respectively, related to the stated interest rate and $0.1 million and $0.1 million, respectively, related to the amortization of debt issuance costs. For the three and six months ended June 30, 2023, interest expense related to the Notes was $0.6 million and $1.2 million, respectively, which included $0.6 million and $1.1 million, respectively, related to the stated interest rate and $51,000 and $0.1 million, respectively, related to the amortization of debt issuance costs. As of June 30, 2024, the carrying value of the Notes was $149.6 million, which is comprised of the $150.0 million principal amount of the Notes outstanding, less debt issuance costs of $0.4 million.

9. Stockholders' Deficit

2023 Private Placement

On July 21, 2023, we entered into a Securities Purchase Agreement (the "July 2023 Private Placement") with Rubric Capital Management L.P., Velan Capital, Clearline Capital and Hercules Capital, Inc. (collectively, the "Purchasers") whereby we sold 20.7 million shares of our common stock in a private placement at a purchase price of $1.37 per share. In addition, as a component of the July 2023 Private Placement, we sold 1.2 million pre-funded warrants to purchase shares of our common stock at a purchase price of $1.3699 per share (the "July 2023 Pre-Funded Warrants"). The July 2023 Pre-Funded Warrants have an exercise price of $0.0001 per share. The total net proceeds from the sale of the common stock and the July 2023 Pre-Funded Warrants was $29.8 million (net of $0.2 million in issuance costs). The July 2023 Private Placement closed on July 25, 2023. In August 2023, we filed a registration statement with the SEC to register for resale 21.9 million shares of our common stock. The registration statement was declared effective on August 31, 2023.

10. Equity Incentive Plan

Option Plan Activity

The following table summarizes the stock option activity for the six months ended June 30, 2024:

	Shares (in thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Outstanding at December 31, 2023	24,575	$ 7.06	5.60
Granted	6,826	$ 2.23	
Exercised	(372)	$ 2.46	
Expired and forfeited	(3,584)	$ 11.17	
Outstanding at June 30, 2024	27,445	$ 5.38	7.74

We estimated the fair value of each option grant on the grant date using the Black-Scholes option pricing model and for market-based stock option grants using the Monte Carlo simulation model. The following are the weighted-average assumptions:

	For the Six Months Ended June 30,	
	2024	2023
Risk-free interest rate	4.2%	3.6%
Dividend yield	0.0%	0.0%
Volatility	74.9%	67.4%
Expected life (years)	6 to 10	6 to 10

We estimated the fair value of each purchase right granted under our 1997 Employee Stock Purchase Plan, as amended, at the beginning of each new offering period using the Black-Scholes option pricing model. The following are the weighted average assumptions:

	For the Six Months Ended June 30,	
	2024	2023
Risk-free interest rate	5.4%	5.1%
Dividend yield	0.0%	0.0%
Volatility	83.6%	97.1%
Expected life (months)	6	6

The following table summarizes the restricted stock unit activity (“RSUs”) for the six months ended June 30, 2024:

	Shares (in thousands)	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2023	1,405	$ 4.43
Granted	1,482	$ 2.30
Released	(829)	$ 2.63
Expired and forfeited	(415)	$ 3.67
Outstanding at June 30, 2024	1,642	$ 2.97

The fair value of RSUs is estimated based on the closing market price of our common stock on the date of the grant. RSUs generally vest quarterly over a four-year period.

Stock-Based Compensation

The following table summarizes stock-based compensation expense related to stock-based payment awards granted pursuant to all of our equity compensation arrangements (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	$ 553	$ 2,694	$ 1,254	$ 4,430
General and administrative	2,060	6,925	3,938	10,457
Sales and marketing	1,957	4,281	2,753	6,960
Total stock-based compensation expense	$ 4,570	$ 13,900	$ 7,945	$ 21,847

As of June 30, 2024, there was $23.6 million of total unrecognized compensation cost related to non-vested, stock-based payment awards granted under all of our equity compensation plans and all non-plan option grants. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. We expect to recognize this compensation cost over a weighted-average period of three years.

11. Income Taxes

Deferred income tax assets and liabilities are recognized for temporary differences between financial statements and income tax carrying values using tax rates in effect for the years such differences are expected to reverse. Due to uncertainties surrounding our ability to generate future taxable income and consequently realize such deferred income tax assets, a full valuation allowance has been established. We continue to maintain a full valuation allowance against our deferred tax assets as of June 30, 2024.

The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant tax authority. An uncertain income tax position will be recognized when it is more likely than not of being sustained. The disclosures regarding uncertain tax positions included in our Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the SEC on March 12, 2024, continue to be accurate for the three and six months ended June 30, 2024.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the U.S. Securities and Exchange Commission ("SEC") on March 12, 2024 (the "2023 Annual Report").

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the federal securities laws. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In some cases, you can identify forward-looking statements by the use of the words "believe," "expect," "anticipate," "intend," "estimate," "project," "will," "would," "could," "should," "may," "might," "plan," "assume" and other expressions that predict or indicate future events and trends and which do not relate to historical matters. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business and commercialization strategy, products and product candidates, research pipeline, ongoing and planned preclinical studies and clinical trials, regulatory submissions and approvals, addressable patient population, research and development expenses, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. You should not rely on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, some of which are beyond our control. These risks, uncertainties and other factors may cause our actual results, performance or achievements to be materially different from our anticipated future results, performance or achievements expressed or implied by the forward-looking statements.

Factors that might cause these differences include the following:

- our ability to successfully commercialize, market and achieve market acceptance of ZYNRELEF® (bupivacaine and meloxicam) extended-release solution ("ZYNRELEF"), APONVIE® (aprepitant) injectable emulsion ("APONVIE"), CINVANTI® (aprepitant) injectable emulsion ("CINVANTI"), and SUSTOL® (granisetron) extended-release injection ("SUSTOL" and together with ZYNRELEF, APONVIE and CINVANTI, our "Products") in the United States ("U.S.") , and our positioning relative to products that now or in the future compete with our Products or product candidates;
- our estimates regarding the potential market opportunities for our Products and our product candidates, if approved, and our ability to capture the potential additional market opportunity from the expanded ZYNRELEF label recently approved in the U.S.;
- our ability to establish and maintain successful commercial arrangements like our co-promotion agreement with CrossLink Life Sciences, LLC ("CrossLink");
- the realization of anticipated benefits from our co-promotion agreement with CrossLink;
- the outcome of our pending abbreviated new drug application litigation;
- whether we are required to write-off any additional inventory in the future;
- our ability to establish satisfactory pricing and obtain adequate reimbursement from government and third-party payors of our Products and product candidates that receive regulatory approvals;
- whether study results of our Products and product candidates are indicative of the results in future studies;
- the results of the commercial launch of APONVIE in the U.S.;
- the potential regulatory approval for, and commercial launch, of our product candidates, if approved;
- our competitors' activities, including decisions as to the timing of competing product launches, generic entrants, pricing and discounting;
- whether safety and efficacy results of our clinical studies and other required tests for expansion of the indications for our Products and approval of our product candidates provide data to warrant progression of clinical trials, potential regulatory approval or further development of any of our Products or product candidates;

- our ability to develop, acquire and advance product candidates into, and successfully complete, clinical studies, and our ability to submit for and obtain regulatory approval for product candidates in our anticipated timing, or at all;
- our ability to meet the postmarketing study requirements within the mandated timelines of the U.S. Food and Drug Administration ("FDA")and to obtain favorable results and comply with standard postmarketing requirements, including U.S. federal advertising and promotion laws, federal and state anti-fraud and abuse laws, healthcare information privacy and security laws, safety information, safety surveillance and disclosure of payments or other transfers of value to healthcare professionals and entities for Products or any of our product candidates;
- our ability to successfully develop and achieve regulatory approval for any product candidates utilizing our proprietary Biochronomer® drug delivery technology (“Biochronomer Technology”);
- our ability to establish key collaborations and vendor relationships for our Products and our product candidates;
- our ability to successfully develop and commercialize any technology that we may in-license or products we may acquire;
- our reliance on third-party contract manufacturers to supply our Products and product candidates, if approved;
- unanticipated delays due to manufacturing difficulties, supply constraints or changes in the regulatory environment, including as a result of geopolitical uncertainty;
- our ability to successfully operate in non-U.S. jurisdictions in which we may choose to do business, including compliance with applicable regulatory requirements and laws;
- uncertainties associated with obtaining and enforcing patents and trade secrets to protect our Products, our product candidates, our Biochronomer Technology and our other technology;
- our ability to successfully defend ourselves against unforeseen third-party infringement claims and other litigation involving our Products and product candidates;
- our estimates regarding our capital requirements;
- the impact of our 2023 restructuring activities, including the reduced headcount and external spend;
- our inability or delay in achieving profitability;
- the impact of evolving legal and regulatory requirements, including emerging environmental, social and governance requirements;
- our ability to obtain additional financing and raise capital as necessary to fund operations or pursue business opportunities; and
- those risks listed under the section entitled "Risk Factors" in Part I, Item 1A of the 2023 Annual Report.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements were based on information, plans and estimates as of the date of this Quarterly Report on Form 10-Q, and except as required by law, we assume no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes. These risk factors may be updated by our future filings under the Securities Exchange Act of 1934, as amended (“Exchange Act”). You should carefully review all information therein.

Overview

We are a commercial-stage biotechnology company focused on improving the lives of patients by developing and commercializing therapeutic innovations that improve medical care. Our advanced science, patented technologies, and innovative approach to drug discovery and development have allowed us to create and commercialize a portfolio of products that aim to advance the standard of care for acute care and oncology patients.

Acute Care Product Portfolio

Our Acute Care Product Portfolio consists of ZYNRELEF, which is approved in the U.S. for the management of postoperative pain and APONVIE, which is approved in the U.S. for the prevention of postoperative nausea and vomiting.

ZYNRELEF

ZYNRELEF was initially approved by the FDA in May 2021, and we commenced commercial sales in the U.S. in July 2021. In each of December 2021 and January 2024, the FDA approved an expansion of ZYNRELEF's indication. ZYNRELEF is approved for small-to-medium open abdominal, lower extremity total joint arthroplasty, soft tissue and orthopedic surgical procedures including foot and ankle, and other procedures in which direct exposure to articular cartilage is avoided.

ZYNRELEF is a dual-acting local anesthetic that delivers a fixed-dose combination of the local anesthetic bupivacaine and a low dose of the nonsteroidal anti-inflammatory drug meloxicam. ZYNRELEF is the first and only modified-release local anesthetic to be classified by the FDA as an extended-release product because ZYNRELEF demonstrated in Phase 3 studies significantly reduced pain and significantly increased proportion of patients requiring no opioids through the first 72 hours following surgery compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control.

In May 2024, we submitted a prior approval supplement (“PAS”) for the addition of a vial access needle (“VAN”) in the ZYNRELEF co-packaged combination product kit. The FDA accepted the VAN PAS for filing and set a Prescription Drug User Fee Act goal date of September 23, 2024. If approved, the introduction of the VAN will replace the current vented vial spike and has the potential to simplify aseptic preparation, while also significantly reducing ZYNRELEF's withdrawal time from up to three minutes down to between twenty and forty-five seconds. The user-friendly "container-like" design of the VAN may enhance the safe use of ZYNRELEF, increase adoption, and improve the preparation process. If approved, the VAN is expected to be available for use in the fourth quarter of this year.

In January 2024, we entered into a five-year distributor partnership with CrossLink to expand the sales network supporting ZYNRELEF. CrossLink will be the lead partner in the U.S. to expand ZYNRELEF promotion for orthopedic indications. The partnership will launch in several phases, initially at a regional level, followed by an expanded national rollout. In total, we anticipate that approximately 650 representatives will be added to Heron’s sales network over 2024.

In March 2022, the Centers for Medicare and Medicaid Services (“CMS”) approved a 3-year transitional pass-through status of ZYNRELEF, which became effective on April 1, 2022, for separate reimbursement outside of the surgical bundle payment in the Hospital Outpatient Department setting of care. In addition, in December 2022, H.R. 2617, the omnibus spending bill was approved by Congress. The bill includes the Non-Opioids Prevent Addiction in the Nation (NOPAIN) Act which directs CMS to provide separate Medicare reimbursement for non-opioid treatments that are used to manage pain during surgeries conducted in hospital outpatient departments or in ambulatory surgical centers. To qualify, the non-opioid treatment must demonstrate the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal. The hospital outpatient prospective payment system and ambulatory surgical center proposed rule for calendar year 2025 includes ZYNRELEF as a qualifying non-opioid requiring CMS to provide separate Medicare reimbursement in both the hospital outpatient department and ambulatory surgical center settings from January 1, 2025 through December 31, 2027.

APONVIE

APONVIE was approved by the FDA in September 2022 and became commercially available in the U.S. in March 2023. APONVIE is indicated for the prevention of postoperative nausea and vomiting (“PONV”) in adults. CMS granted pass-through payment status for APONVIE, effective April 1, 2023.

APONVIE is the first and only intravenous formulation of a substance P/neurokinin-1 (“NK1”) receptor antagonist indicated for PONV. Delivered via a single 30-second intravenous (“IV”) injection, APONVIE has demonstrated rapid achievement of therapeutic drug levels ideally suited for the surgical setting.

Oncology Care Product Portfolio

Our Oncology Care Product portfolio consists of SUSTOL and CINVANTI, which are both approved in the U.S. for the prevention of chemotherapy-induced nausea and vomiting.

SUSTOL

SUSTOL was approved by the FDA in August 2016, and we commenced commercial sales in the U.S. in October 2016.

SUSTOL is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens. SUSTOL is an extended-release, injectable 5-hydroxytryptamine type 3 ("5-HT3") receptor antagonist that utilizes our Biochronomer Technology to maintain therapeutic levels of granisetron for ≥5 days. The SUSTOL global Phase 3 development program was comprised of two, large, guideline-based clinical studies that evaluated SUSTOL's efficacy and safety in more than 2,000 patients with cancer. SUSTOL's efficacy in preventing nausea and vomiting was evaluated in both the acute phase (0–24 hours following chemotherapy) and the delayed phase (24–120 hours following chemotherapy).

SUSTOL is the first extended-release 5-HT3 receptor antagonist approved for the prevention of acute and delayed nausea and vomiting associated with both MEC and AC combination chemotherapy regimens. A standard of care in the treatment of breast cancer and other cancer types, AC regimens are among the most commonly prescribed HEC regimens, as defined by both the National Comprehensive Cancer Network ("NCCN") and the American Society of Clinical Oncology ("ASCO").

In February 2017, the NCCN included SUSTOL as a part of its NCCN Clinical Practice Guidelines in Oncology for Antiemesis Version 1.2017. The NCCN has given SUSTOL a Category 1 recommendation, the highest-level category of evidence and consensus, for use in the prevention of acute and delayed nausea and vomiting in patients receiving HEC or MEC regimens. The guidelines now identify SUSTOL as a "preferred" agent for preventing nausea and vomiting following MEC. Further, the guidelines highlight the unique, extended-release formulation of SUSTOL.

In January 2018, a product-specific billing code, or permanent J-code ("J-code"), for SUSTOL became available. The new J-code was assigned by CMS and has helped simplify the billing and reimbursement process for prescribers of SUSTOL.

CINVANTI

CINVANTI was approved by the FDA in November 2017, and we commenced commercial sales in the U.S. in January 2018. In each of February 2019 and October 2019, the FDA approved an expansion of CINVANTI of its administration and indication, respectively.

CINVANTI, in combination with other antiemetic agents, is indicated in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin as a single-dose regimen, delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single-dose regimen, and nausea and vomiting associated with initial and repeat courses of MEC as a 3-day regimen.

CINVANTI is an IV formulation of aprepitant, a substance NK1 receptor antagonist. CINVANTI is the first IV formulation to directly deliver aprepitant, the active ingredient in EMEND® capsules. Aprepitant (including its prodrug, fosaprepitant) is a single-agent NK1 receptor antagonist to significantly reduce nausea and vomiting in both the acute phase (0–24 hours after chemotherapy) and the delayed phase (24–120 hours after chemotherapy). CINVANTI is the first IV formulation of an NK1 receptor antagonist indicated for the prevention of acute and delayed nausea and vomiting associated with HEC and nausea and vomiting associated with MEC that is free of synthetic surfactants, including polysorbate 80.

NK1 receptor antagonists are typically used in combination with 5-HT3 receptor antagonists. Unlike CINVANTI many other injectable NK1 receptor antagonists currently approved in the U.S. for both acute and delayed chemotherapy induced nausea and vomiting ("CINV"), EMEND® IV (fosaprepitant), contains polysorbate 80, a synthetic surfactant, which has been linked to hypersensitivity reactions, including anaphylaxis, and infusion site reactions. The CINVANTI formulation does not contain polysorbate 80 or any other synthetic surfactant. Our CINVANTI data has demonstrated the bioequivalence of CINVANTI to EMEND IV, supporting its efficacy for the prevention of both acute and delayed nausea and vomiting associated with HEC and nausea and vomiting associated with MEC. Results also showed CINVANTI was better tolerated in healthy volunteers than EMEND IV, with significantly fewer adverse events reported with CINVANTI.

In January 2019, a J-code for CINVANTI became available. The new J-code was assigned by CMS and has helped simplify the billing and reimbursement process for prescribers of CINVANTI.

Biochronomer Technology

Our proprietary Biochronomer Technology is designed to deliver therapeutic levels of a wide range of otherwise short-acting pharmacological agents over a period from days to weeks with a single administration. Our Biochronomer Technology consists of polymers that have been the subject of comprehensive animal and human toxicology studies that have shown evidence of the safety of the polymer. When administered, the polymers undergo controlled hydrolysis, resulting in a controlled, sustained release of the pharmacological agent encapsulated within the Biochronomer-based composition. Furthermore, our Biochronomer Technology is designed to permit more than one pharmacological agent to be incorporated, such that multimodal therapy can be delivered with a single administration.

Critical Accounting Estimates

The discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis, including those related to revenue recognition, investments, inventory and the related reserves, accrued research and development expenses, income taxes and stock-based compensation. We base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances, the results of which form the basis of making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

Our critical accounting estimates include: revenue recognition, investments, inventory and the related reserves, accrued research and development expenses, income taxes, and stock-based compensation. There have been no material changes to our critical accounting estimates disclosures included in our 2023 Annual Report.

Recent Accounting Pronouncements

See Note 3 to the condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

Results of Operations for the Three and Six Months Ended June 30, 2024 and 2023

Net Product Sales

For the three and six months ended June 30, 2024, net product sales were $36.0 million and $70.7 million, respectively, compared to $31.8 million and $61.4 million, respectively, for the same periods in 2023.

Net Product Sales – Acute Care

For the three and six months ended June 30, 2024, net product sales of ZYNRELEF were $5.8 million and $10.8 million, respectively, compared to $4.1 million and $7.7 million, respectively, for the same periods in 2023. For the three and six months ended June 30, 2024, net product sales of APONVIE were $1.0 million and $1.5 million, respectively, compared to $0.3 million and $0.6 million, respectively, for the same periods in 2023. The increase in net product sales for both ZYNRELEF and APONVIE is attributed to an increase in the units sold in 2024 as compared to 2023.

Net Product Sales – Oncology Care

For the three and six months ended June 30, 2024, net product sales of CINVANTI were $24.9 million and $50.5 million, respectively, compared to $24.5 million and $47.3 million, respectively, for the same periods in 2023. For the three and six months ended June 30, 2024, net product sales of SUSTOL were $4.3 million and $7.9 million, respectively, compared to $2.9 million and $5.8 million, respectively, for the same periods in 2023. The increase in net product sales for both CINVANTI and SUSTOL is attributed to an increase in the units sold in 2024 as compared to 2023.

Cost of Product Sales

For the three and six months ended June 30, 2024, cost of product sales was $10.5 million and $19.0 million, respectively, compared to $20.2 million and $37.0 million, respectively, for the same periods in 2023. Cost of product sales primarily included raw materials, labor and overhead related to the manufacturing of our Products, as well as shipping and distribution costs. For the three and six months ended June 30, 2024, cost of product sales included charges of $1.6 million relating to reserves and write-offs of inventory. For the three and six months ended June 30, 2023, cost of product sales included charges of $7.5 million and $12.8 million, respectively, relating to the write-off of inventory. The remaining decrease in cost of product sales is attributed to a decrease in cost per units for CINVANTI and ZYNRELEF, as large-scale manufacturing was validated and approved in late 2022.

Research and Development Expense

Research and development expense consisted of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
ZYNRELEF-related costs	$ 1,083	$ 3,471	$ 1,719	$ 5,627
SUSTOL-related costs	400	370	490	651
CINVANTI-related costs	925	461	1,396	1,286
APONVIE-related costs	92	1,203	294	1,896
Personnel costs and other expenses	1,379	5,011	3,887	8,156
Stock-based compensation expense	553	2,694	1,254	4,430
Total research and development expense	$ 4,432	$ 13,210	$ 9,040	$ 22,046

For the three and six months ended June 30, 2024, research and development expense was $4.4 million and $9.0 million, respectively, compared to $13.2 million and $22.0 million, respectively, for the same periods in 2023. The decrease in research and development expense was primarily due to our decreased headcount and related costs as a result of the restructuring implemented in 2023, as well as a decrease in non-cash, stock-based compensation expense. The decrease is also due to decreases in costs related to ZYNRELEF, as large-scale manufacturing was approved in 2022, and APONVIE as a result of the product becoming commercially available in March 2023.

General and Administrative Expense

For the three and six months ended June 30, 2024, general and administrative expense was $13.9 million and $28.9 million, respectively, compared to $19.6 million and $35.4 million, respectively, for the same periods in 2023. The decrease was primarily due to our decreased headcount and related costs as a result of the restructuring implemented in 2023 and operational efficiencies.

Sales and Marketing Expense

For the three and six months ended June 30, 2024, sales and marketing expense was $13.6 million and $25.1 million, respectively, compared to $21.2 million and $42.4 million, respectively, for the same period in 2023. The decrease was primarily due to our decreased headcount and related costs as a result of the restructuring implemented in 2023 and operational efficiencies.

Other (Expense) Income, Net

For the three and six months ended June 30, 2024, other expense, net was $2.8 million and $1.2 million, respectively, compared to other income, net of $0.3 million and $0.6 million, respectively, for the same period in 2023. The increase in other expense is attributed to increased interest expense as a result of the working capital facility agreement entered into in August 2023 (see Note 8 for further discussion of our working capital facility agreement) and the write-off of property and equipment during the three months ended June 30, 2024, which was associated with a project for which we had a one-time settlement related to a legal dispute during the three months ended March 31, 2024.

Liquidity and Capital Resources

The Company's short-term and long-term liquidity requirements primarily arise from funding (i) sales and marketing expenses, (ii) general and administrative expenses including salaries, bonuses and commissions, (iii) working capital requirements, and (iv) research and development expenses, and (v) payments related to our outstanding convertible notes. As of June 30, 2024, we had cash, cash equivalents and short-term investments of $67.3 million. Based on our current operating plan and projections, management believes that the Company's cash, cash equivalents, short-term investments and working capital facility, will be sufficient to meet the Company's anticipated cash requirements for a period of at least the next twelve months from the date this Quarterly Report on Form 10-Q is filed with the SEC. Our future cash requirements and the adequacy of our available funds will depend on many factors, primarily including our ability to generate revenue and the scope and costs of our commercial and research and development activities.

Our net loss for the three and six months ended June 30, 2024 was $9.2 million, or $0.06 per share, and $12.4 million, or $0.08 per share, respectively, compared to $42.1 million, or $0.35 per share and $74.8 million, or $0.63 per share, respectively, for the same period in 2023.

Our net cash used in operating activities for the six months ended June 30, 2024 and June 30, 2023 was $14.1 million and $52.1 million, respectively. The decrease in net cash used in operating activities was primarily due to a decrease in net loss as a result of decreases in operating spend, primarily as a result of the restructuring implemented in 2023, partially offset by $3.4 million of write-offs of property and equipment during the six months ended June 30, 2024, changes in working capital, specifically accounts receivable due to timing of collections, inventory as a result of write-offs incurred during the six months ended June 30, 2024, accounts payable and accrued expenses due to timing of payments and accrued payroll and employee liabilities due to reduced headcount.

Our net cash provided by investing activities for the six months ended June 30, 2024 and June 30, 2023 was $3.3 million, and $50.1 million, respectively. The decrease in cash provided by investing activities was primarily due to net maturities of short-term investments of $4.0 million for the six months ended June 30, 2024 compared to $50.6 million for the six months ended June 30, 2023.

Our net cash provided by financing activities for the six months ended June 30, 2024 and June 30, 2023 was $0.5 million, and $0.1 million, respectively.

Historically, we have financed our operations, including technology and product research and development, primarily through sales of our common stock, product sales and debt financings.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required for smaller reporting companies.

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports, filed or submitted under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, including, without limitation, controls and procedures designed to ensure that information required to be disclosed in such reports is accumulated and communicated to our management, including our principal executive officer, principal financial officer, and principal accounting officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may become inadequate because of changes in conditions or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our principal executive officer, principal financial officer and principal accounting officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our principal executive officer, principal financial officer, and principal accounting officer concluded that our disclosure controls and procedures were effective as of such time.

There were no changes in our internal control over financial reporting that occurred during the quarter covered by this Quarterly Report on Form 10-Q that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Except as discussed below, there are no material changes from the legal proceedings previously disclosed in our most recently filed Annual Report on Form 10-K for the year ended December 31, 2023.

On June 14, 2022, the Company received a Notice Letter (the "Fresenius Kabi Notice") from Fresenius Kabi advising that Fresenius Kabi had submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of CINVANTI in the U.S. prior to the expiration of U.S. Patent Nos.: 9,561,229; 9,808,465; 9,974,742; 9,974,793; 9,974,794; 10,500,208; 10,624,850; 10,953,018; and 11,173,118 (the "CINVANTI Patents"), which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). The Fresenius Kabi Notice alleges that the CINVANTI Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the generic product described in Fresenius Kabi's ANDA. On July 27, 2022, the Company filed a complaint for patent infringement of the CINVANTI Patents against Fresenius Kabi and a related entity in the U.S. District Court for the District of Delaware in response to Fresenius Kabi's ANDA filing. The complaint seeks, among other relief, equitable relief enjoining Fresenius Kabi from infringing the CINVANTI Patents. On May 15, 2024, the Court granted partial summary judgment of infringement for the Company and found no indefiniteness of U.S. Patent Nos. 9,561,229 and 9,974,794. On June 24, 2024, the parties completed a four-day bench trial centered on Fresenius's defense of obviousness of claims from U.S. Patent Nos. 9,561,229 and 9,974,794 that cover CINVANTI. The parties are currently conducting post-trial briefing. The Company intends to vigorously enforce its intellectual property rights relating to CINVANTI. As a result of filing our complaint for patent infringement, the FDA may not approve Fresenius's ANDA until the earlier of December 14, 2024 or resolution of the litigation

On August 4, 2023, the Company received a Notice Letter (the "Mylan August Notice") from Mylan Pharmaceuticals Inc. ("Mylan") advising that Mylan had submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of CINVANTI ("Mylan's ANDA for a generic version of CINVANTI") in the U.S. prior to the expiration of the CINVANTI Patents, which are listed in the Orange Book. The Mylan August Notice alleges that the CINVANTI Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the generic product described in Mylan's ANDA for a generic version of CINVANTI. On September 15, 2023, the Company filed a complaint for patent infringement of the CINVANTI Patents against Mylan in the U.S. District Court for the District of Delaware in response to the filing of Mylan's ANDA for a generic version of CINVANTI. The complaint seeks, among other relief, equitable relief enjoining Mylan from infringing the CINVANTI Patents. On November 9, 2023, the Company received an updated Notice Letter from Mylan advising that it had submitted an amendment to Mylan's ANDA to include a paragraph IV certification to Heron's recently listed U.S. Patent No. 11,744,800.The parties are currently conducting fact discovery. A five-day bench trial is scheduled for May 19, 2025. The Company intends to vigorously enforce its intellectual property rights relating to CINVANTI. As a result of filing our complaint for patent infringement, the FDA may not approve Mylan's ANDA for a generic version of CINVANTI until the earlier of February 4, 2026 or resolution of the litigation.

On December 16, 2023, the Company received a Notice Letter (the "Mylan December Notice") from Mylan advising that Mylan had submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of APONVIE in the U.S. ("Mylan's ANDA for a generic version of APONVIE") prior to the expiration of U.S. Patent Nos.: 9,561,229; 9,808,465; 9,974,742; 9,974,793; 9,974,794; 10,500,208; 10,624,850; 10,953,018; 11,173,118; and 11,744,800 (the "APONVIE Patents"), which are listed in the Orange Book. The Mylan December Notice Letter alleges that the APONVIE Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the generic product described in Mylan's ANDA for a generic version of APONVIE. On January 11, 2024, the Company filed a complaint for patent infringement of the APONVIE Patents against Mylan in the U.S. District Court for the District of Delaware in response to Mylan filing an ANDA for a generic version of APONVIE. The complaint seeks, among other relief, equitable relief enjoining Mylan from infringing the APONVIE Patents. On January 26, 2024, the Court consolidated this litigation concerning Mylan's ANDA for a generic version of APONVIE with the previously-filed litigation concerning Mylan's ANDA for a generic version of CINVANTI. Accordingly, a five-day bench trial is scheduled for May 19, 2025. The Company intends to vigorously enforce its intellectual property rights relating to APONVIE. As a result of filing our complaint for patent infringement, the FDA may not approve Mylan's ANDA for a generic version of APONVIE until the earlier of June 16, 2026 or resolution of the litigation.

On December 12, 2023, the Company received a Notice Letter (the "Slayback Notice") from Slayback Pharma LLC ("Slayback") advising that Slayback had submitted an NDA under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act to the FDA seeking approval to manufacture, use or sell a generic version of CINVANTI in the U.S. ("Slayback's NDA") prior to the expiration of the patents, listed in the Orange Book. The Slayback Notice alleges that the CINVANTI Patents are invalid,

unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the generic product described in Slayback's NDA. On January 24, 2024, the Company filed a complaint for patent infringement of the CINVANTI Patents against Slayback and a related entity in the U.S. District Court for the District of New Jersey in response to Slayback's NDA filing. The complaint seeks, among other relief, equitable relief enjoining Slayback from infringing those patents. On July 2, 2024, the U.S. District Court for the District of New Jersey granted Slayback's motion to transfer this matter to the U.S. District Court for the District of Delaware. The trial in the U.S. District Court for the District of Delaware is not yet scheduled. The Company intends to vigorously enforce its intellectual property rights relating to CINVANTI. As a result of filing our complaint for patent infringement, the FDA may not approve Slayback's NDA until the earlier of June 12, 2026 or resolution of the litigation.

ITEM 1A. RISK FACTORS

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in this report, the risks and uncertainties that we believe are most important for you to consider are discussed in Part I, "Item 1A. Risk Factors" in the 2023 Form 10-K and in Part II, "Item 1A. Risk Factors" in our subsequently filed Quarterly Reports on Form 10-Q. Other than the factors set forth below, there have been no material changes to the risk factors described in the 2023 Form 10-K.

We face intense competition from other companies developing products for the management of postoperative pain or the prevention of CINV and PONV.

ZYNRELEF competes in the postoperative pain management market with MARCAINETM (bupivacaine hydrochloride injection, solution, marketed by Pfizer Inc.) and generic forms of bupivacaine; NAROPIN® (ropivacaine, marketed by Fresenius Kabi USA, LLC) and generic forms of ropivacaine; EXPAREL® (bupivacaine liposome injectable suspension, marketed by Pacira BioSciences, Inc.); XARACOLL®(bupivacaine HCl implant, marketed by Innocoll Pharmaceuticals Limited); POSIMIR® (owned by Durect Corporation and to be marketed in the U.S. by Innocoll Pharmaceuticals Limited); ANJESO® (meloxicam injection, marketed by Baudax Bio, Inc.); OFIRMEV® (acetaminophen injection, marketed by Mallinckrodt Pharmaceuticals); SEGLENTIS® (celecoxib and tramadol hydrochloride, marketed by Kowa Pharmaceuticals America, Inc. in the U.S.); generic forms of IV acetaminophen; and potentially other products in development for postoperative pain management that reach the U.S. market.

APONVIE competes in the PONV prevention market with generic ondansetron, the current standard of care, generic aprepitant, and BARHEMSYS® (amisulpride, marketed by Eagle Pharmaceuticals, Inc.); TAK-951 (a peptide agonist under development (PH2) by Takeda Pharmaceutical Company Limited for PONV and not approved anywhere globally for any use); and potentially other products in development for PONV prevention that reach the market.

CINVANTI faces significant competition. NK1 receptor antagonists are administered for the prevention of CINV, in combination with 5-HT3 receptor antagonists, to augment the therapeutic effect of the 5-HT3 receptor antagonist. Currently available NK1receptor antagonists include: generic versions of EMEND® IV (fosaprepitant); EMEND® IV (fosaprepitant, marketed by Merck & Co., Inc.); EMEND® (aprepitant, marketed by Merck & Co., Inc.); AKYNZEO®(palonosetron, a 5-HT3 receptor antagonist, combined with netupitant, an NK1 receptor antagonist, marketed by Helsinn Therapeutics (U.S.), Inc.); VARUBI® (rolapitant, marketed by TerSera Therapeutics LLC), FOCINVEZ™ (fosaprepitant injection, marketed by Amneal Pharmaceuticals, LLC) and other products that include an NK1 receptor antagonist that reach the market for the prevention of CINV.

SUSTOL faces significant competition. Currently available 5-HT3 receptor antagonists include: AKYNZEO® (palonosetron, a 5-HT3 receptor antagonist, combined with netupitant, an NK1 receptor antagonist, marketed by Helsinn Therapeutics (U.S.), Inc.); SANCUSO® (granisetron transdermal patch, marketed by Cumberland Pharmaceuticals Inc.); and generic products including ondansetron (formerly marketed by GlaxoSmithKline plc as ZOFRAN), granisetron (formerly marketed by Hoffman-La Roche, Inc. as KYTRIL) and palonosetron (formerly marketed by Eisai in conjunction with Helsinn Healthcare S.A. as ALOXI). Currently, palonosetron is the only 5-HT3receptor antagonist other than SUSTOL that is approved for the prevention of delayed CINV associated with MEC regimens. SUSTOL is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens, which is considered to be a HEC regimen by the NCCN and ASCO. No other 5-HT3 receptor antagonist is specifically approved for the prevention of delayed CINV associated with a HEC regimen.

Small or early-stage companies and research institutions may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, and acquiring and in-licensing technologies and products complementary to our programs or potentially advantageous to our business. If any of our competitors succeed in obtaining approval from the FDA or other regulatory authorities for their product candidates sooner than we do for our product candidates that are more effective or less costly than ours, our commercial opportunity could be significantly reduced. Major technological changes can happen quickly in the biotechnology and pharmaceutical industries, and the development of technologically improved or different products or drug delivery technologies may make our product candidates or platform technologies obsolete or noncompetitive.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description
3.1	Certificate of Incorporation, as amended through July 29, 2009 (incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, as Exhibit 3.1, filed on August 9, 2009)
3.2	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.1, filed on June 30, 2011)
3.3	Certificate of Amendment to the Certificate of Incorporation (incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.1, filed on January 13, 2014
3.4	Certificate of Amendment to the Certificate of Incorporation (incorporated by reference to our Company's Post-Effective Amendment to its Registration Statement on Form 8-A/A, filed on July 6, 2017)
3.5	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2018, as exhibit 3.6, filed on February 22, 2019)
3.6	Certificate of Amendment to the Certificate of Incorporation (incorporated by reference to our Current Report on Form 8-K, as exhibit 3.1, filed on June 12, 2023)
3.7	Certificate of Amendment to the Certificate of Incorporation (incorporated by reference to our Current Report on Form 8-K, as exhibit 3.1, filed on June 18, 2024)
3.8	Amended and Restated Bylaws (incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.1, filed on February 8, 2019)
31.1+	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2+	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Extension Definition
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document included as Exhibit 101)

+ Filed herewith
++ Furnished herewith

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.

Heron Therapeutics, Inc.

Date: August 6, 2024

/s/ Craig Collard

Craig Collard
Chief Executive Officer
(As Principal Executive Officer)

/s/ Ira Duarte

Ira Duarte
Executive Vice President, Chief Financial Officer
(As Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 31.1

SECTION 302 CERTIFICATION

I, Craig Collard, certify that:

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

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

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

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

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

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our 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 our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: August 6, 2024

/s/ Craig Collard

Craig Collard
Chief Executive Officer
(As Principal Executive Officer)

EXHIBIT 31.2

SECTION 302 CERTIFICATION

I, Ira Duarte, certify that:

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

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

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

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

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

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our 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 our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: August 6, 2024

/s/ Ira Duarte

Ira Duarte
Executive Vice President, Chief Financial Officer
(As 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

Each of the undersigned, in their capacity as Principal Executive Officer and Principal Financial Officer, respectively, of Heron Therapeutics, Inc. (the "Registrant"), hereby certifies, for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his or her knowledge that:

- the Quarterly Report of the Registrant on Form 10-Q for the quarter ended June 30, 2024 (the "Report"), which accompanies this certification, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition of the Registrant at the end of such quarter and the results of operations of the Registrant for such quarter.

Dated: August 6, 2024

/s/ Craig Collard
Craig Collard
Chief Executive Officer
(As Principal Executive Officer)

/s/ Ira Duarte
Ira Duarte
Executive Vice President, Chief Financial Officer
(As Principal Financial Officer and Principal Accounting Officer)

This certification accompanies the Report to which it relates, is not deemed to be filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Heron Therapeutics, Inc. 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.

Note: A signed original of this written statement required by Section 906 has been provided to Heron Therapeutics, Inc. and will be retained by Heron Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.