

**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 **September 30, 2023**

OR

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

For the transition period from _____ to _____

Commission file number: **001-33221**

HERON THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

94-2875566

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

**4242 Campus Point Court, Suite 200
San Diego, CA**

(Address of principal executive offices)

92121

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

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

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

The number of shares of the registrant's common stock, par value \$0.01 per share, outstanding as of November 10, 2023 was 150,072,640.

FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2023

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

HERON THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(In thousands)

	<u>September 30, 2023</u>	<u>December 31, 2022</u>
	(Unaudited)	(See Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 34,859	\$ 15,364
Short-term investments	42,553	69,488
Accounts receivable, net	63,795	52,049
Inventory	42,007	54,573
Prepaid expenses and other current assets	10,765	13,961
Total current assets	193,979	205,435
Property and equipment, net	20,785	22,160
Right-of-use lease assets	6,069	7,645
Other assets	8,366	15,711
Total assets	<u>\$ 229,199</u>	<u>\$ 250,951</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,860	\$ 3,225
Accrued clinical and manufacturing liabilities	24,740	24,468
Accrued payroll and employee liabilities	10,376	13,416
Other accrued liabilities	39,770	38,552
Current lease liabilities	2,999	2,694
Total current liabilities	79,745	82,355
Non-current lease liabilities	3,537	5,499
Non-current notes payable, net	24,023	—
Non-current convertible notes payable, net	149,439	149,284
Other non-current liabilities	241	241
Total liabilities	256,985	237,379
Stockholders' equity (deficit):		
Common stock	1,411	1,191
Additional paid-in capital	1,866,094	1,807,855
Accumulated other comprehensive loss	(1)	(19)
Accumulated deficit	(1,895,290)	(1,795,455)
Total stockholders' equity (deficit)	(27,786)	13,572
Total liabilities and stockholders' equity	<u>\$ 229,199</u>	<u>\$ 250,951</u>

See accompanying notes.

HERON THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Net product sales	\$ 31,434	\$ 26,557	\$ 92,811	\$ 77,644
Cost of product sales	18,208	14,717	55,220	42,247
Gross profit	13,226	11,840	37,591	35,397
Operating expenses:				
Research and development	13,558	25,545	44,947	96,449
General and administrative	11,641	9,799	37,724	28,513
Sales and marketing	12,956	18,378	55,315	64,738
Total operating expenses	38,155	53,722	137,986	189,700
Loss from operations	(24,929)	(41,882)	(100,395)	(154,303)
Other income (expense), net	(79)	(26)	560	(7,852)
Net loss	(25,008)	(41,908)	(99,835)	(162,155)
Other comprehensive income (loss):				
Unrealized gains (losses) on short-term investments	5	(46)	18	(51)
Comprehensive loss	\$ (25,003)	\$ (41,954)	\$ (99,817)	\$ (162,206)
Basic and diluted net loss per share	\$ (0.17)	\$ (0.38)	\$ (0.75)	\$ (1.54)
Weighted average common shares outstanding, basic and diluted	144,990	111,735	133,747	105,456

See accompanying notes.

HERON THERAPEUTICS, INC.

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	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 gains on short-term investments	—	—	—	28	—	28
Comprehensive loss	—	—	—	—	—	(32,740)
Balance as of March 31, 2023	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 losses on short-term investments	—	—	—	(15)	—	(15)
Comprehensive loss	—	—	—	—	—	(42,074)
Balance as of June 30, 2023	119,956	1,199	1,829,805	(6)	(1,870,282)	(39,284)
Issuance of common stock under equity incentive plan	410	4	(312)	—	—	(308)
Issuance of common stock in private placement	20,735	208	29,547	—	—	29,755
Issuance of warrants in debt financing	—	—	371	—	—	371
Stock-based compensation expense	—	—	6,683	—	—	6,683
Net loss	—	—	—	—	(25,008)	(25,008)
Net unrealized gains on short-term investments	—	—	—	5	—	5
Comprehensive loss	—	—	—	—	—	(25,003)
Balance as of September 30, 2023	141,101	\$ 1,411	\$ 1,866,094	\$ (1)	\$ (1,895,290)	\$ (27,786)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance as of December 31, 2021	102,005	\$ 1,020	\$ 1,689,987	\$ (6)	\$ (1,613,431)	\$ 77,570
Issuance of common stock under equity incentive plan	138	1	(638)	—	—	(637)
Stock-based compensation expense	—	—	10,915	—	—	10,915
Net loss	—	—	—	—	(63,888)	(63,888)
Net unrealized losses on short-term investments	—	—	—	(2)	—	(2)
Comprehensive loss	—	—	—	—	—	(63,890)
Balance as of March 31, 2022	102,143	1,021	1,700,264	(8)	(1,677,319)	23,958
Issuance of common stock under equity incentive plan	154	2	(459)	—	—	(457)
Issuance of common stock under the employee stock purchase plan	201	2	770	—	—	772
Stock-based compensation expense	—	—	10,353	—	—	10,353
Net loss	—	—	—	—	(56,359)	(56,359)
Net unrealized losses on short-term investments	—	—	—	(3)	—	(3)
Comprehensive loss	—	—	—	—	—	(56,362)
Balance as of June 30, 2022	102,498	\$ 1,025	\$ 1,710,928	\$ (11)	\$ (1,733,678)	\$ (21,736)
Issuance of common stock in a private placement, net	16,129	161	75,002	—	—	75,163
Issuance of common stock under equity incentive plan	147	2	(223)	—	—	(221)
Stock-based compensation expense	—	—	11,198	—	—	11,198
Net loss	—	—	—	—	(41,908)	(41,908)
Net unrealized losses on short-term investments	—	—	—	(46)	—	(46)
Comprehensive loss	—	—	—	—	—	(41,954)
Balance as of September 30, 2022	118,774	\$ 1,188	\$ 1,796,905	\$ (57)	\$ (1,775,586)	\$ 22,450

See accompanying notes.

HERON THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2023	2022
Operating activities:		
Net loss	\$ (99,835)	\$ (162,155)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	28,530	32,466
Depreciation and amortization	2,184	2,098
Amortization of debt discount	21	—
Amortization of debt issuance costs	155	152
Accretion of discount on short-term investments	(1,173)	(162)
Impairment of property and equipment	463	130
Loss on disposal of property and equipment	23	74
Change in operating assets and liabilities:		
Accounts receivable	(11,746)	(6,689)
Inventory	12,566	(3,857)
Prepaid expenses and other assets	10,541	5,726
Accounts payable	(1,365)	2,744
Accrued clinical and manufacturing liabilities	272	13,582
Accrued payroll and employee liabilities	(3,040)	(555)
Other accrued and other non-current liabilities	1,160	7,068
Net cash used in operating activities	<u>(61,244)</u>	<u>(109,378)</u>
Investing activities:		
Purchases of short-term investments	(64,309)	(127,115)
Maturities and sales of short-term investments	92,435	122,957
Purchases of property and equipment	(1,295)	(1,411)
Proceeds from the sale of property and equipment	—	224
Net cash provided by (used in) investing activities	<u>26,831</u>	<u>(5,345)</u>
Financing activities:		
Net proceeds from private placement	29,755	75,163
Net proceeds from note financing	24,350	—
Payments for stock issued under the equity incentive plan	(901)	(1,315)
Proceeds from purchases under the employee stock purchase plan	704	772
Net cash provided by financing activities	<u>53,908</u>	<u>74,620</u>
Net increase (decrease) in cash and cash equivalents	19,495	(40,103)
Cash and cash equivalents at beginning of year	15,364	90,541
Cash and cash equivalents at end of period	<u>\$ 34,859</u>	<u>\$ 50,438</u>
Supplemental disclosure of cash flow information:		
Interest paid	<u>\$ 1,288</u>	<u>\$ 1,125</u>

See accompanying notes.

HERON THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements (Unaudited)

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. HTX-034, an investigational agent, is our next-generation product candidate which has been evaluated for the management of postoperative pain. With the recent change of the executive management team, we decided to pause the development of HTX-034 to evaluate the program and market potential going forward.

As of September 30, 2023, we had cash, cash equivalents and short-term investments of \$77.4 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 U.S. (“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 nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for other quarters or the year ending December 31, 2023. The condensed consolidated balance sheet as of December 31, 2022 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, 2022, which was filed with the SEC on March 29, 2023.

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 loss and realized gains and losses included in other income (expense). 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).

Our bank and investment accounts have been placed under a control agreement in accordance with our Working Capital Line of Credit (see Note 9).

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.

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 product sales and accounts receivable balances for our three major Customers, each of which comprised 10% or more of our product sales:

	Product Sales		Accounts Receivable
	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2023	As of September 30, 2023
Customer A	43.6%	42.7%	44.7%
Customer B	37.3%	37.2%	37.0%
Customer C	18.5%	19.1%	18.0%
Total	99.4%	99.0%	99.7%

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. 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.

We offered extended payment terms to our Customers in connection with our product launch of APONVIE in March 2023. As of September 30, 2023 and December 31, 2022, we determined that an allowance for credit losses was not required. For the three and nine months ended September 30, 2023 and 2022, we did not have any material write-offs of accounts receivable balances.

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.

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 lease agreements with both lease and non-lease components, which are generally accounted for separately.

Revenue Recognition

Revenue is recognized in accordance with the Financial Accounting Standards Board (the “FASB”) Accounting Standards Codification (“ASC”) Topic 606, *Revenue from Contracts with Customers* (“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 5 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 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 GPOs’ 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
CINVANTI net product sales	\$ 23,270	\$ 21,169	\$ 70,599	\$ 64,173
SUSTOL net product sales	3,439	2,671	9,258	7,179
ZYNRELEF net product sales	4,372	2,717	12,033	6,292
APONVIE net product sales	353	—	921	—
Total net product sales	\$ 31,434	\$ 26,557	\$ 92,811	\$ 77,644

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, 2022	\$ 3,336	\$ 4,180	\$ 25,801	\$ 33,317
Provision	2,092	17,420	128,232	147,744
Payments/credits	(921)	(17,335)	(127,194)	(145,450)
Balance at September 30, 2023	\$ 4,507	\$ 4,265	\$ 26,839	\$ 35,611

Comprehensive Loss

Comprehensive 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 common shares 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):

	September 30,	
	2023	2022
Stock options outstanding	31,317	20,500
Restricted stock units outstanding	1,786	2,817
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 consolidated financial statements or related financial statement 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):

	Balance at September 30, 2023	Fair Value Measurements at Reporting Date Using		
		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	\$ 29,198	\$ 29,198	\$ —	\$ —
U.S. treasury bills and government agency obligations	32,068	32,068	—	—
U.S. corporate debt securities	8,048	—	8,048	—
Foreign corporate debt securities	4,164	—	4,164	—
U.S. commercial paper	1,962	—	1,962	—
Foreign commercial paper	1,972	—	1,972	—
Total	\$ 77,412	\$ 61,266	\$ 16,146	\$ —

	Balance at December 31, 2022	Fair Value Measurements at Reporting Date Using		
		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	\$ 13,867	\$ 13,867	\$ —	\$ —
U.S. treasury bills and government agency obligations	35,715	35,715	—	—
U.S. corporate debt securities	1,497	—	1,497	—
U.S. commercial paper	5,481	—	5,481	—
Foreign commercial paper	28,292	—	28,292	—
Total	\$ 84,852	\$ 49,582	\$ 35,270	\$ —

We have not transferred any investment securities between the three levels of the fair value hierarchy.

As of September 30, 2023, cash equivalents included \$5.6 million of available-for-sale securities with contractual maturities of three months or less and short-term investments included \$42.6 million of available-for-sale securities with contractual maturities of three months to one year. As of December 31, 2022, cash equivalents included \$1.5 million of available-for-sale securities with contractual maturities of three months or less and short-term investments included \$69.5 million of available-for-sale securities with contractual maturities of three months to one year. The money market funds as of September 30, 2023 and December 31, 2022 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 convertible notes outstanding at September 30, 2023 and December 31, 2022 do not have a readily available ascertainable market value, however, the carrying value is considered to approximate its fair value.

5. Short-term Investments

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

	September 30, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury bills and government agency obligations	\$ 28,091	\$ 1	\$ —	\$ 28,092
U.S. corporate debt securities	8,049	—	(1)	8,048
Foreign corporate debt securities	2,480	—	(1)	2,479
U.S. commercial paper	1,962	—	—	1,962
Foreign commercial paper	1,972	—	—	1,972
Total	<u>\$ 42,554</u>	<u>\$ 1</u>	<u>\$ (2)</u>	<u>\$ 42,553</u>

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury bills and government agency obligations	\$ 35,734	\$ —	\$ (19)	\$ 35,715
U.S. commercial paper	5,481	—	—	5,481
Foreign commercial paper	28,292	—	—	28,292
Total	<u>\$ 69,507</u>	<u>\$ —</u>	<u>\$ (19)</u>	<u>\$ 69,488</u>

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 nine months ended September 30, 2023 and 2022.

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 recognized \$1,000 in realized losses during the three and nine months ended September 30, 2023. We did not recognize any realized gains or losses during the three and nine months ended September 30, 2022.

6. Inventory

Inventory consists of the following (in thousands):

	September 30, 2023	December 31, 2022
Raw materials	\$ 15,611	\$ 15,137
Work in process	16,421	20,723
Finished goods	9,975	18,713
Total inventory	<u>\$ 42,007</u>	<u>\$ 54,573</u>

As of September 30, 2023, total inventory included \$25.7 million related to CINVANTI, \$12.7 million related to ZYNRELEF, \$2.8 million related to SUSTOL and \$0.8 million related to APONVIE. As of December 31, 2022, total inventory included \$19.9 million related to CINVANTI, \$30.9 million related to ZYNRELEF, \$2.6 million related to SUSTOL and \$1.2 million for APONVIE. For the three and nine months ended September 30, 2023, cost of product sales included charges of \$7.5 million and \$20.3 million, respectively, compared to \$2.0 million and \$4.5 million, respectively, for the same periods in 2022, resulting from the write-off of ZYNRELEF inventory.

7. Leases

As of September 30, 2023, 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 5-year option to renew this lease on expiration applies only with respect to our remaining 28,275 square feet of laboratory and office space.

In September 2023, we also entered into a sublease agreement to sublet 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 nine months ended September 30, 2023, we recognized \$0.7 million and \$2.1 million, respectively, of operating lease expense and we paid \$0.5 million and \$2.2 million, respectively, for our operating leases. During the three and nine months ended September 30, 2022, we recognized \$0.7 million and \$2.1 million, respectively, of operating lease expense and we paid \$0.7 million and \$2.1 million, respectively, for our operating leases.

Annual future minimum lease payments as of September 30, 2023 are as follows (in thousands):

2023	\$ 772
2024	3,153
2025	3,138
2026	—
Total future minimum lease payments	<u>\$ 7,063</u>
Less: discount	(527)
Total lease liabilities	<u>\$ 6,536</u>

8. Reorganizations

June 2023 Reorganization

In June 2023, we implemented a restructuring plan under which we provided or will provide employees one-time severance payments upon termination, continuation of benefits for a specific period of time, outplacement services and certain stock award modifications. The total amount expected to be incurred for these activities is \$3.9 million, which primarily consists of severance payments to terminated employees. During the three months ended September 30, 2023, we recognized \$1.9 million of the total expense, \$1.0 million of which was included in sales and marketing expense and \$0.9 million of which was included in research and development expense. During the nine months ended September 30, 2023, we recognized \$3.7 million of the total expense, \$2.1 million of which was included in sales and marketing expense, \$1.5 million of which was included in research and development expense, and \$0.1 million of which was included in general and administrative expense. We expect to recognize the remaining \$0.2

million of expense during the fourth quarter of 2023. As of September 30, 2023, we have paid \$1.7 million of the total cash severance charges. We anticipate that the cash payments due to terminated employees will be substantially complete in the first quarter of 2024.

Executive Officer Departures

During the second and third quarters of 2023, we also implemented changes to our executive leadership structure. In connection with these changes, we provided five executive officers with one-time severance payments upon termination, continued benefits for a specified period of time, and certain stock option modifications. The total expense for these activities was \$13.4 million, \$4.7 million of which was primarily for severance and \$8.7 million of which was for non-cash, stock-based compensation expense. During the three months ended September 30, 2023, we recognized \$2.2 million of the total expense, all of which was included in general and administrative expense. During the nine months ended September 30, 2023, we recognized \$13.4 million of the total expense, \$7.2 million of which was included in general and administrative expense, \$3.9 million of which was included in sales and marketing expense, and \$2.3 million of which was included in research and development expense. As of September 30, 2023, we have paid \$4.6 million of the total cash severance charges.

June 2022 Reorganization

In June 2022, we implemented a restructuring plan under which we provided employees one-time severance payments upon termination, continuation of benefits for a specific period of time, outplacement services and certain stock award modifications. The total amount incurred for these activities was \$5.4 million, \$5.0 million of which was primarily for severance and \$0.4 million of which was for non-cash, stock-based compensation expense related to stock award modifications. As of September 30, 2023, we have paid all of the total cash severance charges.

We have accounted for these expenses in accordance with the FASB ASC Topic 420, *Exit or Disposal Cost Obligations*.

9. 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 tranching 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 existing senior unsecured convertible notes (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, as of closing, 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 warrants are equal to 2.00% of the principal amount of 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 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 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 September 30, 2023.

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 warrants issued upon closing to purchase 297,619 shares of our common stock 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 297,619 issued 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 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 both the three and nine months ended September 30, 2023, interest expense related to the Loan Agreement was \$467,000, which included \$376,000 related to the stated interest rate, \$55,000 related to paid-in-kind interest, and \$36,000 related to the amortization of the debt discounts. As of September 30, 2023, the carrying value of tranche 1A was \$24.0 million, which is comprised of the \$25.0 million principal amount outstanding, less debt discounts of \$1.0 million.

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 (“Notes”). We received a total of \$149.0 million, net of issuance costs, from the issuance of these 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 15th and December 15th of each year, beginning on December 15, 2021. The Notes mature on May 26, 2026, unless earlier converted, redeemed or repurchased.

The Notes will be 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 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 own 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 months ended September 30, 2023, interest expense related to the Notes was \$615,000, which included \$563,000 related to the stated interest rate and \$52,000 related to the amortization of debt issuance costs. For the three months ended September 30, 2022, interest expense related to the Notes was \$614,000, which included \$563,000 related to the stated interest rate and \$51,000 related to the amortization of debt issuance costs. For both the nine months ended September 30, 2023 and 2022, interest expense related to the Notes was \$1.8 million, which included \$1.7 million related to the stated interest rate and \$0.1 million related to the amortization of debt issuance costs. As of September 30, 2023, the carrying value of the Notes was \$149.4 million, which is comprised of the \$150.0 million principal amount of the Notes outstanding, less debt issuance costs of \$0.6 million.

10. Stockholders' Equity

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 pre-funded warrants have an exercise price of \$0.0001 per share. The total net proceeds from the sale of the common stock and pre-funded warrants is \$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.

2022 Private Placement

On August 8, 2022, we entered into an agreement to sell 16.1 million shares of our common stock in a private placement at a purchase price of \$3.10 per share ("2022 Private Placement"). In addition, as a component of the 2022 Private Placement, we agreed to sell 8.5 million pre-funded warrants to purchase shares of our common stock at a purchase price of \$3.0999 per share. The pre-funded warrants have an exercise price of \$0.0001 per share. The total net proceeds from the sale of the common stock and pre-funded warrants was \$75.1 million (net of \$1.4 million in issuance costs). The 2022 Private Placement closed on August 10, 2022. In October 2022, we filed a registration statement with the SEC to register for resale 24.6 million shares of our common stock. The registration statement was declared effective on October 18, 2022.

11. Equity Incentive Plan

Option Plan Activity

The following table summarizes the stock option activity for the nine months ended September 30, 2023:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Outstanding at December 31, 2022	20,749,349	\$ 14.61	6.44
Granted	16,116,979	\$ 1.70	
Exercised	(369)	\$ 1.32	
Expired and forfeited	(5,548,978)	\$ 9.47	
Outstanding at September 30, 2023	<u>31,316,981</u>	\$ 8.88	6.53

The following table summarizes the restricted stock unit activity (“RSUs”) for the nine months ended September 30, 2023:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2022	3,167,397	\$ 6.46
Granted	1,757,506	\$ 2.39
Released	(1,351,303)	\$ 6.48
Expired and forfeited	(1,787,579)	\$ 4.21
Outstanding at September 30, 2023	<u>1,786,021</u>	<u>\$ 4.68</u>

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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	\$ 2,308	\$ 4,921	\$ 9,092	\$ 13,906
General and administrative	2,874	2,932	10,977	8,717
Sales and marketing	1,501	3,345	8,461	9,843
Total stock-based compensation expense	<u>\$ 6,683</u>	<u>\$ 11,198</u>	<u>\$ 28,530</u>	<u>\$ 32,466</u>

As of September 30, 2023, there was \$30.4 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 3 years.

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.

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 Nine Months Ended September 30,	
	2023	2022
Risk-free interest rate	3.7 %	3.1 %
Dividend yield	0.0 %	0.0 %
Volatility	68.1 %	61.1 %
Expected life (years)	6 to 10	6

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. There were no new offering periods during the three months ended September 30, 2023.

12. 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 September 30, 2023.

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, 2022, which was filed with the SEC on March 29, 2023, continue to be accurate for the three and nine months ended September 30, 2023.

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, 2022, which was filed with the U.S. Securities and Exchange Commission (“SEC”) on March 29, 2023.

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”), CINVANTI[®] (aprepitant) injectable emulsion (“CINVANTI”), SUSTOL[®] (granisetron) extended-release injection (“SUSTOL”) and APONVIE[®] (aprepitant) injectable emulsion (“APONVIE”) in the United States (“U.S.”) (collectively, our “Products”), and our positioning relative to products that now or in the future compete with our Products or product candidates;
- the timing of the U.S. Food and Drug Administration’s (“FDA”) review process, whether and to what degree the FDA approves our currently pending, and any future, supplemental New Drug Application (“sNDA”) for ZYNRELEF to further expand the U.S. label, and our ability to capture the potential additional market opportunity for any expanded U.S. label;
- 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 any product candidates, if approved;
- the potential market opportunities for our Products and any 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 FDA’s mandated timelines 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;
- 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, and our ability to successfully defend ourselves against unforeseen third-party infringement claims;
- our estimates regarding our capital requirements;
- the impact of our restructuring activities, including the reduced headcount and external spend;
- the impact of evolving legal and regulatory requirements, including emerging environmental, social and governance requirements; and
- our ability to obtain additional financing and raise capital as necessary to fund operations or pursue business opportunities.

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 and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled “Risk Factors” in Part I, Item 1A of our 2022 Annual Report on Form 10-K. You should carefully review all of these factors. 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 (“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

ZYNRELEF

ZYNRELEF was initially approved by the FDA in May 2021, and we commenced commercial sales in the U.S. in July 2021. In December 2021, the FDA approved our sNDA for ZYNRELEF, which significantly expanded the indication statement. ZYNRELEF is currently indicated for use in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures.

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 December 2022, we submitted an sNDA to the FDA requesting expansion of the indication statement for ZYNRELEF to broadly cover soft tissue and orthopedic surgical procedures. This sNDA is based on safety and pharmacokinetic data from clinical trials in total shoulder arthroplasty, spinal surgery, abdominoplasty, and C-section showing comparable results to the previously completed pivotal safety and efficacy trials of ZYNRELEF. The FDA accepted the sNDA for filing and set a Prescription Drug User Fee Act (“PDUFA”) goal date of October 23, 2023. On July 31, 2023, Heron was notified by the FDA that the FDA was extending the goal date by three months to provide time for a full review of the submission. The FDA set a new extended PDUFA goal date of January 23, 2024.

In the fourth quarter of 2022, we validated large-scale manufacturing of our proprietary polymer and ZYNRELEF, which will allow for the manufacturing of millions of doses of ZYNRELEF annually at a significantly reduced cost of product sales.

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 that includes a provision requiring CMS to pay for certain non-opioids outside the existing bundled payment for surgeries for the period January 1, 2025 to December 31, 2027.

ZYNRELEF was granted a marketing authorization by the European Commission (“EC”) in September 2020 and by the United Kingdom (“U.K.”) Regulatory Authority in January 2021. In August 2023, we cancelled the U.K. ZYNRELEF marketing authorization and, in October 2023, we cancelled the ZYNRELEF marketing authorization in the European Union (“EU”), as we do not plan to commercially launch ZYNRELEF in the U.K., the EU, or the other countries in the European Economic Area.

Health Canada issued a Notice of Compliance to commercialize ZYNRELEF in March 2022. In the second quarter of 2023, we withdrew our new drug submission, as we do not plan to commercially launch ZYNRELEF in Canada.

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

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.

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 the only 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 and only 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. The only other injectable NK₁ receptor antagonist 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.

In February 2019, the FDA approved our sNDA for CINVANTI, for IV use, which expanded the administration of CINVANTI beyond the initially approved administration method (a 30-minute IV infusion) to include a 2-minute IV injection.

In October 2019, the FDA approved our sNDA for CINVANTI to expand the indication and recommended dosage to include the 130 mg single-dose regimen for patients receiving MEC.

In the fourth quarter of 2022, we validated larger-scale manufacturing of CINVANTI, which will significantly reduce the cost of product sales.

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 U.S. generally accepted accounting principles. 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 Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on March 29, 2023.

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 Nine Months Ended September 30, 2023 and 2022

Net Product Sales

For the three and nine months ended September 30, 2023, net product sales were \$31.4 million and \$92.8 million, respectively, compared to \$26.6 million and \$77.6 million, respectively, for the same periods in 2022.

Net Product Sales – Acute Care

For the three and nine months ended September 30, 2023, net product sales of ZYNRELEF were \$4.4 million and \$12.0 million, respectively, compared to \$2.7 million and \$6.3 million, respectively, for the same periods in 2022. For the three and nine months ended September 30, 2023, net product sales of APONVIE were \$0.3 million and \$0.9 million, respectively. APONVIE became commercially available in the U.S. in March 2023.

Net Product Sales – Oncology Care

For the three and nine months ended September 30, 2023, net product sales of CINVANTI were \$23.3 million and \$70.6 million, respectively, compared to \$21.2 million and \$64.2 million, respectively, for the same periods in 2022. For the three and nine months ended September 30, 2023, net product sales of SUSTOL were \$3.4 million and \$9.3 million, respectively, compared to \$2.7 million and \$7.1 million, respectively, for the same periods in 2022.

Cost of Product Sales

For the three and nine months ended September 30, 2023, cost of product sales was \$18.2 million and \$55.2 million, respectively, compared to \$14.7 million and \$42.2 million, respectively, for the same periods in 2022. 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 nine months ended September 30, 2023, cost of product sales also included charges of \$7.5 million and \$20.3 million, respectively, compared to \$2.0 million and \$4.5 million, respectively, for the three and nine months ended September 30, 2022, resulting primarily from the write-off of ZYNRELEF inventory.

We began capitalizing raw materials, labor and overhead related to the manufacturing of APONVIE following FDA approval in September 2022. There were no costs incurred prior to FDA approval for the commercial manufacturing of APONVIE.

Research and Development Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
ZYNRELEF-related costs	\$ 2,516	\$ 6,940	\$ 9,833	\$ 44,555
SUSTOL-related costs	348	248	1,010	1,558
CINVANTI-related costs	367	3,055	1,551	5,132
APONVIE-related costs	1,714	115	3,564	843
HTX-034-related costs	67	304	83	591
Personnel costs and other expenses	6,238	9,962	19,814	29,864
Stock-based compensation expense	2,308	4,921	9,092	13,906
Total research and development expense	<u>\$ 13,558</u>	<u>\$ 25,545</u>	<u>\$ 44,947</u>	<u>\$ 96,449</u>

For the three and nine months ended September 30, 2023, research and development expense was \$13.6 million and \$44.9 million, respectively, compared to \$25.5 million and \$96.4 million, respectively, for the same periods in 2022. The decrease was primarily due to decreases in costs related to ZYNRELEF and CINVANTI, as production scale-up, validation activities and raw materials qualification were completed in 2022. In addition, the decrease in research and development expense was due to decreases in personnel and related costs as a result of the savings from the June 2022 reduction in force, as well as a decrease in non-cash, stock-based compensation expense.

General and Administrative Expense

For the three and nine months ended September 30, 2023, general and administrative expense was \$11.6 million and \$37.7 million, respectively, compared to \$9.8 million and \$28.5 million, respectively, for the same periods in 2022. The increase was primarily due to severance and non-cash, stock-based compensation expense in connection with executive departures in the second and third quarters of 2023, and ongoing legal costs associated with the CINVANTI patent litigation.

Sales and Marketing Expense

For the three and nine months ended September 30, 2023, sales and marketing expense was \$13.0 million and \$55.3 million, respectively, compared to \$18.4 million and \$64.7 million, respectively, for the same periods in 2022. The decrease was primarily due to a decrease in costs to support the ongoing commercialization of ZYNRELEF, due to improved operational efficiencies.

Other Income (Expense), Net

For the three and nine months ended September 30, 2023, other income (expense), net was (\$0.1) million and \$0.6 million, respectively, compared to other expense, net of \$26,000 and \$7.9 million, respectively, for the same periods in 2022. The change for the three and nine months ended September 30, 2023 was primarily due to the write-off of property and equipment at a third-party manufacturing site in 2022, as well as an increase in interest income earned on our invested cash balances in 2023.

Restructuring Plans

See Note 8 to the condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q for discussion of the June 2022 Reorganization and the June 2023 Reorganization.

Liquidity and Capital Resources

As of September 30, 2023, we had cash, cash equivalents and short-term investments of \$77.4 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 SEC.

Our net loss for the three and nine months ended September 30, 2023 was \$25.0 million, or \$0.17 per share, and \$99.8 million, or \$0.75 per share, respectively, compared to a net loss of \$41.9 million, or \$0.38 per share, and \$162.2 million, or \$1.54 per share, respectively, for the same periods in 2022.

Our net cash used in operating activities for the nine months ended September 30, 2023 was \$61.2 million, compared to \$109.4 million for the same period in 2022. The decrease in net cash used in operating activities was primarily due to a decrease in net loss, partially offset by changes in working capital.

Our net cash provided by investing activities for the nine months ended September 30, 2023 was \$26.8 million, compared to net cash used for investing activities of \$5.3 million for the same period in 2022. The increase in cash provided by investing activities was primarily due to net maturities of short-term investments of \$28.1 million for the nine months ended September 30, 2023, compared to net purchases of short-term investments of \$4.2 million for the same period in 2022.

Our net cash provided by financing activities for the nine months ended September 30, 2023 was \$53.9 million, compared to \$74.6 million for the same period in 2022. The decrease in cash provided by financing activities was primarily due to net proceeds of \$54.1 million received from debt and equity financings completed in the third quarter of 2023, compared to net proceeds of \$75.2 million received from the August 2022 private placement.

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

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 tranching 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 existing senior unsecured convertible notes (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, as of closing, 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.

For both the three and nine months ended September 30, 2023, interest expense related to the Loan Agreement was \$467,000, which included \$376,000 related to the stated interest rate, \$55,000 related to paid-in-kind interest, and \$36,000 related to the amortization of the debt discounts. As of September 30, 2023, the carrying value of tranche 1A was \$24.0 million, which is comprised of the \$25.0 million principal amount outstanding, less debt discounts of \$1.0 million. We were in compliance with all covenants of the Loan Agreement as of September 30, 2023. For more information on the Loan Agreement, see Note 9 "Convertible Notes" to the condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

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 under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information 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.

As required by Exchange Act Rule 13a-15(b), we carried out an evaluation under the supervision and with the participation of our management, including our principal executive officer, principal financial officer, and principal accounting officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our principal executive officer, principal financial officer, and principal accounting officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There were no changes in our internal control over financial reporting that occurred during the quarter covered by this report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On June 14, 2022, the Company received a paragraph IV notice of certification (the “Notice Letter”) from Fresenius Kabi USA, LLC (“Fresenius Kabi”) advising that Fresenius Kabi had submitted an Abbreviated New Drug Application (“Fresenius’s 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 Notice Letter 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’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’s ANDA filing. The complaint seeks, among other relief, equitable relief enjoining Fresenius Kabi from infringing the CINVANTI Patents. The parties are currently completing fact discovery and will be moving into expert discovery. A five-day bench trial is scheduled for June 24, 2024. On October 17, 2023, the Company received an updated Notice Letter from Fresenius Kabi advising that it had submitted an amendment to Fresenius’s ANDA to include a paragraph IV certification to Heron’s recently listed U.S. Patent No. 11,744,800 (the “800 Patent”). 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 14, 2023, the Company received a Notice Letter from Mylan Pharmaceuticals Inc. (“Mylan”) advising that Mylan had submitted an ANDA (“Mylan’s 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 the CINVANTI patents, which are listed in the Orange Book. The Notice Letter 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. On September 15, 2023, the Company filed a complaint for patent infringement of the CINVANTI Patents against Mylan in the Court in response to Mylan’s ANDA filing. The complaint seeks, among other relief, equitable relief enjoining Mylan from infringing the CINVANTI Patents. 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 until the earlier of February 4, 2026 or resolution of the litigation.

ITEM 1A. RISK FACTORS

Our business is subject to various risks, including those described in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022. There have been no material changes from the risk factors disclosed in Item 1A of our Annual Report on Form 10-K.

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

(c) None.

ITEM 6. EXHIBITS

Exhibit Number	Description
10.1	<u>Securities Purchase Agreement, dated July 21, 2023, by and among the Company and the Purchasers signatory thereto (incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on July 24, 2023)</u>
10.2	<u>Working Capital Facility Agreement, dated August 9, 2023, by and among the Company, the several banks and other financial institutions or entities from time to time party thereto, and Hercules, Capital, Inc. (incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, as Exhibit 10.10, filed on August 14, 2023)</u>
31.1+	<u>Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2+	<u>Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1++	<u>Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
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: November 14, 2023

/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)

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: November 14, 2023

/s/ Craig Collard

Craig Collard
Chief Executive Officer
(As Principal Executive Officer)

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: November 14, 2023

/s/ Ira Duarte

Ira Duarte

Executive Vice President, Chief Financial Officer
(As Principal Financial Officer)

**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 September 30, 2023 (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: November 14, 2023

/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)

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.
