

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2023

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: 001-38583

Crinetics Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

10222 Barnes Canyon Road, Bldg. #2,
San Diego, California
(Address of principal executive offices)

26-3744114
(I.R.S. Employer
Identification No.)

92121
(Zip code)

Registrant's telephone number, including area code: (858) 450-6464

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 \$0.001 per share	CRNX	Nasdaq Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input 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

As of August 4, 2023, the registrant had 54,686,550 shares of common stock (\$0.001 per share par value) outstanding.

CRINETICS PHARMACEUTICALS, INC. QUARTERLY REPORT ON FORM 10-Q
For the Quarter Ended June 30, 2023

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Item 1. Condensed Financial Statements

Crinetics Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except per share data)

	June 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 39,553	\$ 32,672
Investment securities	224,976	301,753
Prepaid expenses and other current assets	20,281	10,759
Total current assets	284,810	345,184
Property and equipment, net	3,223	3,500
Operating lease right-of-use asset	1,253	1,486
Derivative asset	668	668
Restricted cash	1,300	1,301
Other assets	2,000	37
Total assets	<u>\$ 293,254</u>	<u>\$ 352,176</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 20,825	\$ 15,351
Accrued compensation and related expenses	8,596	9,081
Deferred revenue	2,080	2,240
Operating lease liability	1,109	1,051
Total current liabilities	32,610	27,723
Operating lease liability, non-current	1,456	2,024
Deferred revenue, non-current	5,072	6,101
Total liabilities	39,138	35,848
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.001 par; 10,000 shares authorized; no shares issued or outstanding on June 30, 2023 or December 31, 2022	—	—
Common stock and paid-in capital, \$0.001 par; 200,000 shares authorized; 54,682 shares issued and outstanding on June 30, 2023; 53,877 shares issued and outstanding on December 31, 2022	791,968	759,432
Accumulated other comprehensive loss	(1,705)	(3,931)
Accumulated deficit	(536,147)	(439,173)
Total stockholders' equity	254,116	316,328
Total liabilities and stockholders' equity	<u>\$ 293,254</u>	<u>\$ 352,176</u>

See the accompanying notes to these unaudited condensed consolidated financial statements.

Crinetics Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except per share data)
(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Revenues	\$ 988	\$ 439	\$ 3,667	\$ 3,570
Operating expenses:				
Research and development	40,640	32,995	79,108	61,247
General and administrative	13,343	10,489	25,532	19,195
Total operating expenses	53,983	43,484	104,640	80,442
Loss from operations	(52,995)	(43,045)	(100,973)	(76,872)
Other income (expense):				
Interest income	2,107	720	4,145	913
Other expense, net	(91)	(81)	(146)	(64)
Change in valuation of derivative asset	—	31	—	31
Total other income, net	2,016	670	3,999	880
Loss before equity method investment	(50,979)	(42,375)	(96,974)	(75,992)
Loss on equity method investment	—	—	—	(1,010)
Net loss	\$ (50,979)	\$ (42,375)	\$ (96,974)	\$ (77,002)
Net loss per share:				
Net loss per share - basic and diluted	\$ (0.94)	\$ (0.81)	\$ (1.79)	\$ (1.54)
Weighted average shares - basic and diluted	54,275	52,522	54,092	50,130
Other comprehensive income (loss):				
Unrealized gain (loss) on investment securities	\$ 809	\$ (1,427)	\$ 2,226	\$ (3,237)
Comprehensive loss	\$ (50,170)	\$ (43,802)	\$ (94,748)	\$ (80,239)

See the accompanying notes to these unaudited condensed consolidated financial statements.

Crinetics Pharmaceuticals, Inc.
Condensed Consolidated Statements of Stockholders' Equity

(in thousands)
(unaudited)

	Common Stock Shares	Common stock and Paid-In Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total Stockholders' Equity
Balance on April 1, 2023	53,990	\$ 768,012	\$ (2,514)	\$ (485,168)	\$ 280,330
Exercise of stock options	94	1,348	—	—	1,348
Stock issued under Employee Stock Purchase Plan	75	1,123	—	—	1,123
Stock-based compensation	—	10,175	—	—	10,175
Issuance of common stock, net of \$0.3 million of transaction costs	523	11,310	—	—	11,310
Comprehensive income	—	—	809	—	809
Net loss	—	—	—	(50,979)	(50,979)
Balance on June 30, 2023	<u>54,682</u>	<u>\$ 791,968</u>	<u>\$ (1,705)</u>	<u>\$ (536,147)</u>	<u>\$ 254,116</u>
Balance on January 1, 2023	53,877	\$ 759,432	\$ (3,931)	\$ (439,173)	\$ 316,328
Exercise of stock options	126	1,832	—	—	1,832
Stock issued under Employee Stock Purchase Plan	75	1,123	—	—	1,123
Restricted stock units vested	81	—	—	—	—
Stock-based compensation	—	18,271	—	—	18,271
Issuance of common stock, net of \$0.3 million of transaction costs	523	11,310	—	—	11,310
Comprehensive income	—	—	2,226	—	2,226
Net loss	—	—	—	(96,974)	(96,974)
Balance on June 30, 2023	<u>54,682</u>	<u>\$ 791,968</u>	<u>\$ (1,705)</u>	<u>\$ (536,147)</u>	<u>\$ 254,116</u>
Balance at April 1, 2022	47,801	\$ 615,118	\$ (2,192)	\$ (309,882)	\$ 303,044
Issuance of common stock, net of \$7.8 million of transaction costs	5,626	117,242	—	—	117,242
Stock issued under Employee Stock Purchase Plan	66	813	—	—	813
Exercise of stock options	227	1,737	—	—	1,737
Stock-based compensation	—	7,131	—	—	7,131
Comprehensive loss	—	—	(1,427)	—	(1,427)
Net loss	—	—	—	(42,375)	(42,375)
Balance at June 30, 2022	<u>53,720</u>	<u>\$ 742,041</u>	<u>\$ (3,619)</u>	<u>\$ (352,257)</u>	<u>\$ 386,165</u>
Balance at January 1, 2022	47,597	\$ 607,581	\$ (382)	\$ (275,255)	\$ 331,944
Issuance of common stock, net of \$7.8 million of transaction costs	5,626	117,242	—	—	117,242
Stock issued under Employee Stock Purchase Plan	66	813	—	—	813
Vesting of shares subject to repurchase	1	2	—	—	2
Exercise of stock options	430	3,517	—	—	3,517
Stock-based compensation	—	12,886	—	—	12,886
Comprehensive loss	—	—	(3,237)	—	(3,237)
Net loss	—	—	—	(77,002)	(77,002)
Balance at June 30, 2022	<u>53,720</u>	<u>\$ 742,041</u>	<u>\$ (3,619)</u>	<u>\$ (352,257)</u>	<u>\$ 386,165</u>

See the accompanying notes to these unaudited condensed consolidated financial statements.

Crinetics Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows

(in thousands)
(unaudited)

	Six months ended June 30,	
	2023	2022
Operating activities:		
Net loss	\$ (96,974)	\$ (77,002)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation	18,271	12,886
Depreciation and amortization	563	455
Noncash lease expense	233	195
Accretion of purchase discounts and amortization of premiums on investment securities, net	(1,441)	517
Loss on equity method investment	—	1,010
Loss on disposal of property and equipment	6	—
Change in valuation of derivative asset	—	(31)
Noncash license revenues	(2,000)	—
Increase (decrease) in cash resulting from changes in:		
Prepaid expenses and other assets	(9,485)	3,234
Accounts payable and accrued expenses	6,073	8,241
Deferred revenue	(1,189)	9,431
Operating lease liability	(510)	(455)
Net cash used in operating activities	<u>(86,453)</u>	<u>(41,519)</u>
Investing activities:		
Purchases of investment securities	(82,165)	(247,572)
Maturities of investment securities	162,609	30,617
Purchases of property and equipment	(253)	(700)
Net cash provided by (used in) investing activities	<u>80,191</u>	<u>(217,655)</u>
Financing activities:		
Proceeds from issuance of common stock, net of \$0.3 million (2023) and \$7.8 million (2022) of transaction costs	11,310	117,255
Proceeds from exercise of stock options	1,832	3,517
Net cash provided by financing activities	<u>13,142</u>	<u>120,772</u>
Net change in cash, cash equivalents and restricted cash	6,880	(138,402)
Cash, cash equivalents and restricted cash at beginning of period	33,973	201,195
Cash, cash equivalents and restricted cash at end of period	<u>\$ 40,853</u>	<u>\$ 62,793</u>
Components of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	\$ 39,553	\$ 62,293
Restricted cash	1,300	500
Cash, cash equivalents and restricted cash at end of period	<u>\$ 40,853</u>	<u>\$ 62,793</u>
Noncash investing and financing activities:		
Stock received under licensing arrangement	\$ 2,000	\$ —
Change in unvested stock liability	\$ —	\$ 2
Stock issued under Employee Stock Purchase Plan	\$ 1,123	\$ 813
Amounts accrued for follow-on offering costs	\$ —	\$ 13
Amounts accrued for purchases of property and equipment	\$ 39	\$ 82

See the accompanying notes to these unaudited condensed consolidated financial statements.

Notes to Unaudited Condensed Consolidated Financial Statements

1. ORGANIZATION AND BASIS OF PRESENTATION**Description of Business**

Crinetics Pharmaceuticals, Inc. (the “Company”) is a clinical-stage pharmaceutical company incorporated in Delaware on November 18, 2008, and based in San Diego, California. The Company is focused on the discovery, development, and commercialization of novel therapeutics for rare endocrine diseases and endocrine-related tumors. In January 2017, the Company established a wholly owned Australian subsidiary, Crinetics Australia Pty Ltd (“CAPL”), in order to conduct various preclinical and clinical activities for its development candidates.

Unaudited Interim Financial Information

The accompanying interim condensed consolidated balance sheet as of June 30, 2023, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2023 and 2022, the condensed consolidated statements of stockholders’ equity for the three and six months ended June 30, 2023 and 2022, and the condensed consolidated statements of cash flows for the six months ended June 30, 2023 and 2022, and the related disclosures are unaudited. In management’s opinion, the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company’s financial position as of June 30, 2023 and the results of its operations and cash flows for the six months ended June 30, 2023 and 2022 in accordance with accounting principles generally accepted in the United States of America (“GAAP”). The results for the three and six months ended June 30, 2023 are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

Principles of Consolidation and Foreign Currency Transactions

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

Segment Reporting

Operating segments are identified as components of an enterprise about which discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

Liquidity

From inception, the Company has devoted substantially all of its efforts to drug discovery and development, and conducting preclinical studies and clinical trials. The Company has a limited operating history, and the sales and income potential of the Company’s business and market are unproven. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company’s cost structure. The Company has experienced net losses and negative cash flows from operating activities since its inception and has an accumulated deficit of \$536.1 million as of June 30, 2023.

As of June 30, 2023, the Company had \$264.5 million in unrestricted cash, cash equivalents and investment securities, which the Company believes is sufficient to meet its funding requirements for at least the next 12 months.

The Company expects to continue to incur net losses for the foreseeable future and believes it will need to raise substantial additional capital to accomplish its business plan over the next several years. The Company plans to continue to fund its losses from operations and capital funding needs through a combination of equity offerings, debt financings or other sources, including potential collaborations, licenses, and other similar arrangements. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, or suspend or curtail planned programs. Any of these actions could materially harm the Company’s business, results of operations and prospects. There can be no assurance as to the availability or terms upon which such financing and capital might be available in the future.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The Company's condensed consolidated financial statements are prepared in accordance with GAAP. The preparation of the Company's condensed consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's condensed consolidated financial statements and accompanying notes. The most significant estimates in the Company's condensed consolidated financial statements relate to accrual of research and development expenses, valuation of stock-based awards, fair values of financial instruments, revenue recognition and investment in Radionetics. Estimates are based on historical experiences or on forecasts, including information received from third parties and various other factors that the Company believes are reasonable under the circumstances. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from those estimates.

Investment in Radionetics

The Company first analyzes its investment in another entity to determine if the entity is a variable interest entity ("VIE") and if so, whether the Company is the primary beneficiary requiring consolidation. An entity is considered a VIE if (1) the entity does not have enough equity to finance its own activities without additional support, (2) the entity's at-risk equity holders lack the characteristics of a controlling financial interest, or (3) the entity is structured with non-substantive voting rights. VIEs are consolidated by the primary beneficiary, which is the entity that has both the power to direct the activities that most significantly impact the VIE's economic performance and the obligation to absorb losses or the right to receive benefits from the VIE that potentially could be significant to the VIE. Variable interests in a VIE can be contractual, ownership, or other financial interests. The Company re-assesses its investment upon reconsideration events to determine whether the Company is the primary beneficiary of the VIE, in which case the Company would consolidate the VIE.

If it has been determined that the Company is not the primary beneficiary or does not have control but does have the ability to exercise significant influence over the VIE, the Company accounts for the unconsolidated investment under the equity method of accounting.

In October 2021, the Company, together with 5AM Ventures ("5AM") and Frazier Healthcare Partners ("Frazier"), announced the formation of Radionetics Oncology, Inc. ("Radionetics"). Radionetics is a VIE. The Company maintains an equity interest in Radionetics and accounts for its investment in Radionetics under the equity method of accounting due to its ability to exercise significant influence. The Company records its share of Radionetics income (loss) outside of operations in the statements of operations and comprehensive loss on a quarterly lag. The Company's equity method investment in Radionetics was written down to zero during the first quarter of 2022 because of the allocation of the Company's share of losses of the investee. As of June 30, 2023, the Company had a 55% ownership stake in Radionetics.

R. Scott Struthers, Ph.D., the Company's President and Chief Executive Officer, serves as chairman of the Radionetics board of directors. Pursuant to such arrangement, Dr. Struthers received 1,000,000 shares of restricted common stock of Radionetics, which vest ratably over 36 months, subject to continued service, and receives a \$50,000 annual retainer for his service as a board member of Radionetics.

As of June 30, 2023 and December 31, 2022, the Company had \$0.1 million due from Radionetics for reimbursement of certain expenses paid on behalf of Radionetics. These amounts are recorded within prepaid expenses and other current assets in the accompanying condensed consolidated balance sheets. The Company earned reimbursements from Radionetics of \$19,000 and \$32,000 for the three and six months ended June 30, 2023, respectively, and \$0.4 million for the six months ended June 30, 2022.

Fair Value Measurements

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

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

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

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions about risk and the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

The carrying amounts of the Company's current financial assets, restricted cash and current financial liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. The Company recorded the derivative asset (see Note 8) and investment securities (see Note 3) at fair value.

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents include cash held in readily available checking and money market accounts, as well as short-term debt securities with maturities of three months or less when purchased. Restricted cash represents cash held as collateral for the Company's facility leases and is reported as a long-term asset in the accompanying condensed consolidated balance sheets.

Investment Securities

All investments have been classified as "available-for-sale" and are carried at fair value as determined based upon quoted market prices or pricing models for similar securities at period end. Investments with contractual maturities less than 12 months at the balance sheet date are considered short-term investments. Investments with contractual maturities beyond one year are also classified as short-term due to the Company's ability to liquidate the investment for use in operations within the next 12 months.

Realized gains and losses on investment securities are derived using the specific identification method for determining the cost of securities sold and are included in other income (expenses), net in the accompanying condensed consolidated statements of operations and comprehensive loss. The Company has not realized any significant gains or losses on sales of available-for-sale debt securities during any of the periods presented. Interest income is recognized when earned and is included in interest income in the accompanying condensed consolidated statements of operations and comprehensive loss, as are the amortization of purchase premiums and accretion of purchase discounts on investment securities.

Effective January 1, 2023, at each balance sheet date, the Company assesses available-for-sale debt securities in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized in net loss. For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through net loss. For available-for-sale securities that do not meet the criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, underlying credit ratings, and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded as an allowance in interest income. There have been no impairment or credit losses recognized during the periods presented in the accompanying condensed consolidated statements of operations and comprehensive loss.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and investment securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash balances due to the financial position of the depository institution in which those deposits are held. Additionally, the Company has established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Leases

The Company determines if an arrangement is a lease at the inception of the arrangement. Leases with a term longer than 12 months that are determined to be operating leases are included in operating lease right-of-use assets, other current liabilities and noncurrent operating lease liabilities in the condensed consolidated balance sheets at the commencement date of the arrangement. The Company accounts for each separate lease and non-lease component as a single lease component. When the Company's leases do not provide an implicit rate, an incremental borrowing rate is used based on the information available at commencement dates in determining the present value of lease payments. The incremental borrowing rate is the rate of interest that the Company would expect to pay to borrow over a similar term, and on a collateralized basis, an amount equal to the lease payments in a similar economic environment. The Company's lease terms may include options to extend or terminate the lease when the Company is reasonably certain that it will exercise such options. Lease expense for lease payments is recognized on a straight-line basis over the lease term. Lease agreements may contain variable costs such as common area maintenance, insurance, taxes, or other costs. Such variable lease costs are expensed as incurred. Lease expense for lease payments is recognized on a straight-line basis over the lease term. The Company assesses its leases to determine whether the arrangements contain lease incentives.

Revenue Recognition

The Company has generated revenue from licensing and supply agreement arrangements. The Company recognizes revenues when, or as, the promised goods or services are transferred to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those services. To determine revenue recognition for arrangements, the Company performs the following five steps: (1) identify the contract(s) with a customer; (2) identify the performance obligation(s) in the contract; (3) determine the

transaction price; (4) allocate the transaction price to the performance obligation(s) in the contract; and (5) recognize revenue when (or as) the performance obligation(s) are satisfied. At contract inception, the Company assesses the goods or services promised within each contract, assesses whether each promised good or service is distinct and identifies those that are performance obligations. The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when, or as, the performance obligation is satisfied.

The Company has entered into licensing and collaboration agreements that mainly include the following: (i) upfront considerations; (ii) payments associated with achieving certain milestones; and (iii) royalties based on specified percentages of net product sales, if any.

The Company has also entered into a manufacturing and supply arrangement that includes reimbursements of costs plus a pre-determined margin.

At the initiation of an agreement, the Company analyzes each unit of account within the contract to determine if the counterparty is a customer in the context of the unit of account.

The Company considers a variety of factors in determining the appropriate estimates and assumptions under the arrangements, such as whether the elements are distinct performance obligations, whether there are observable standalone prices, whether the license is functional or symbolic, and whether the Company is acting as the agent or principal. The Company evaluates each performance obligation to determine if it can be satisfied and recognized as revenue at a point in time or over time.

At the inception of arrangements that include variable consideration, the Company uses judgment to estimate the amount of variable consideration to include in the transaction price using the most likely method. If it is probable that a significant revenue reversal will not occur, then the estimated amount is included in the transaction price. Milestone payments that are not within the Company's or the licensee's control, such as regulatory approvals, are not included in the transaction price until those approvals are received. At the end of each reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint and, as necessary, adjusts the estimate of the overall transaction price. Any adjustments will be recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

The Company develops estimates of the standalone selling price for each distinct performance obligation. Variable consideration that relates specifically to efforts to satisfy specific performance obligations is allocated entirely to those performance obligations. Other components of the transaction price are allocated based on the relative standalone selling price, over which management has applied significant judgment. The Company determines the standalone selling price for license-related performance obligations using a market approach, which may include assumptions such as forecasted revenues, development timelines, discount rates and probabilities of success. The Company estimates the standalone selling price for the data exchange performance obligation (see Note 8) by forecasting the expected costs of satisfying a performance obligation plus a predetermined margin.

In the case of a license that is a distinct performance obligation, the Company recognizes revenue allocated to the license from non-refundable, up-front fees at the point in time when the license is transferred to the licensee and the licensee can use and benefit from the license. For licenses that are bundled with other distinct or combined obligations, the Company uses judgment to assess the nature of the performance obligation to determine whether the performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. If the performance obligation is satisfied over time, then the Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The selection of the method to measure progress towards completion requires judgment and is based on the nature of the products or services to be provided. The Company has used the cost-to-cost measure of progress because it best depicts the transfer of control to the customer which occurs as the Company incurs costs. Under the cost-to-cost measure of progress, the extent of progress towards completion is measured based on the ratio of costs incurred to date to the total estimated costs at completion of the performance obligation, which is considered an input method. The Company uses judgment to estimate the total cost of these performance obligations, which include subcontractors' costs, labor, materials, other direct costs, and an allocation of indirect costs. The Company evaluates these cost estimates and the progress each reporting period and, as necessary, the Company adjusts the measure of progress and related revenue recognition.

Sales-based milestones and royalties are recognized at the later of when the subsequent sale or usage occurs or the performance obligation for which some or all of the sales-based milestones and royalties have been allocated to has been satisfied or partially satisfied.

Research and Development Expenses

Research and development ("R&D") expenses consist primarily of salaries, payroll taxes, employee benefits and stock-based compensation for individuals involved in R&D efforts, as well as consulting expenses, third-party R&D expenses, laboratory supplies, clinical materials and overhead, including facilities and depreciation costs, offset by the Australian Tax Incentive discussed below. R&D expenses are charged to expense as incurred. Payments made prior to the receipt of goods or services to be used in R&D are capitalized until the goods or services are received and are recorded as prepaid expenses and other current assets.

Costs incurred under contracts with contract research organizations that conduct and manage the Company’s clinical trials are also included in R&D expenses. The financial terms and activities of these agreements vary from contract to contract and may result in uneven expense levels. Generally, these agreements set forth activities that drive the recording of expenses such as start-up and initiation activities, enrollment and treatment of patients, or the completion of other clinical trial activities. Expenses related to clinical trials are accrued based on estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies and progress of the clinical trials. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the amounts that the Company is obligated to pay under its clinical trial agreements are modified (for instance, because of changes in the clinical trial protocol or scope of work to be performed), the Company adjusts its accruals accordingly on a prospective basis. Revisions to contractual payment obligations are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

Australian Tax Incentive

CAPL is eligible to obtain a cash refund from the Australian Taxation Office for eligible R&D expenditures under the Australian R&D Tax Incentive Program (the “Australian Tax Incentive”). The Australian Tax Incentive is recognized as a reduction to R&D expense when there is reasonable assurance that the relevant expenditure has been incurred, the amount can be reliably measured and that the Australian Tax Incentive will be received. The Australian Taxation Office has a recapture right for a period of four years.

The Company recognized reductions to R&D expense of \$16,000 and \$37,000 for the three and six months ended June 30, 2023, respectively, and \$0.2 million and \$0.3 million for the three and six months ended June 30, 2022, respectively.

Stock-Based Compensation

Stock-based compensation expense represents the estimated grant date fair value of the Company’s equity awards, consisting of stock options, restricted stock units and shares issued under the Company’s Employee Stock Purchase Plan, recognized over the requisite service period of such awards (usually the vesting period) on a straight-line basis. The Company estimates the fair value of all stock option grants using the Black-Scholes option pricing model and recognizes forfeitures as they occur. Restricted stock units are valued using the grant date stock price. For stock awards for which vesting is subject to performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable, or the performance condition has been achieved.

Comprehensive Loss

Comprehensive loss is comprised of the Company’s net loss and the unrealized gains or losses on the Company’s available for sale investment securities for all periods presented. The cumulative amount of unrealized gains and losses is reflected as a separate component of stockholders' equity in the accompanying condensed consolidated balance sheets as accumulated other comprehensive income (loss).

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock and dilutive common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. Dilutive common stock equivalents are comprised of common stock subject to repurchase and stock options outstanding under the Company’s stock option plan. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as inclusion of the potentially dilutive securities on loss per share would be antidilutive.

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

	As of June 30,	
	2023	2022
Stock options	12,423	8,519
Restricted stock units	843	282
Employee stock purchase plan	268	159
Total	<u>13,534</u>	<u>8,960</u>

Recently Adopted Accounting Pronouncements

ASU 2016-13

In June 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-13, “Financial Instruments - Credit Losses (Topic 326): *Measurement of Credit Losses on Financial Instruments*” (“Topic 326”). Topic 326 amends guidance on reporting credit losses for assets held at amortized cost basis and available for sale debt securities. For assets held at amortized cost basis, Topic 326 eliminates the probable initial recognition threshold in current GAAP and, instead, requires an entity

to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. For available for sale debt securities, credit losses should be measured in a manner like current GAAP, however Topic 326 will require that credit losses be presented as an allowance rather than as a write-down. This ASU update affects entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. This update is effective for the Company for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company adopted ASU 2016-13 as of January 1, 2023, which did not have a material impact on its condensed consolidated financial statements.

3. INVESTMENT SECURITIES

The Company reports its available-for-sale investment securities at their estimated fair values. The following is a summary of the available-for-sale investment securities held by the Company as of June 30, 2023 and December 31, 2022 (in thousands):

	As of June 30, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Available-for-sale investment securities:				
U.S. government and agency obligations	\$ 138,811	\$ 19	\$ (695)	\$ 138,135
Certificates of deposit	3,664	—	(58)	3,606
Corporate debt securities	76,675	—	(971)	75,704
Commercial paper	7,531	—	—	7,531
Total	<u>\$ 226,681</u>	<u>\$ 19</u>	<u>\$ (1,724)</u>	<u>\$ 224,976</u>

	As of December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Available-for-sale investment securities:				
U.S. government and agency obligations	\$ 154,228	\$ 12	\$ (1,510)	\$ 152,730
Certificates of deposit	4,629	—	(94)	4,535
Corporate debt securities	145,330	—	(2,336)	142,994
Asset-backed securities	1,497	—	(3)	1,494
Total	<u>\$ 305,684</u>	<u>\$ 12</u>	<u>\$ (3,943)</u>	<u>\$ 301,753</u>

As of June 30, 2023 and December 31, 2022, available-for-sale investment securities by contractual maturity were as follows (in thousands):

	As of June 30, 2023		As of December 31, 2022	
	Amortized Cost	Fair Market Value	Amortized Cost	Fair Market Value
Available-for-sale investment securities:				
Due in one year or less	\$ 226,190	\$ 224,494	\$ 246,276	\$ 243,542
Due after one year through five years	491	482	59,408	58,211
Total	<u>\$ 226,681</u>	<u>\$ 224,976</u>	<u>\$ 305,684</u>	<u>\$ 301,753</u>

The following is a summary of the available-for-sale investment securities by length of time in a net loss position as of June 30, 2023 and December 31, 2022 (in thousands):

	As of June 30, 2023					
	Less Than 12 Months		More Than 12 Months		Total	
	Fair Market Value	Gross Unrealized Losses	Fair Market Value	Gross Unrealized Losses	Fair Market Value	Gross Unrealized Losses
Available-for-sale investment securities:						
U.S. government and agency obligations	\$ 65,505	\$ (263)	\$ 28,034	\$ (432)	\$ 93,539	\$ (695)
Certificates of deposit	1,206	(19)	2,399	(39)	3,605	(58)
Corporate debt securities	13,019	(160)	57,684	(811)	70,703	(971)
Total	<u>\$ 79,730</u>	<u>\$ (442)</u>	<u>\$ 88,117</u>	<u>\$ (1,282)</u>	<u>\$ 167,847</u>	<u>\$ (1,724)</u>

	As of December 31, 2022					
	Less Than 12 Months		More Than 12 Months		Total	
	Fair Market Value	Gross Unrealized Losses	Fair Market Value	Gross Unrealized Losses	Fair Market Value	Gross Unrealized Losses
Available-for-sale investment securities:						
U.S. government and agency obligations	\$ 95,933	\$ (702)	\$ 36,681	\$ (808)	\$ 132,614	\$ (1,510)
Certificates of deposit	2,399	(47)	2,136	(47)	4,535	(94)
Corporate debt securities	96,663	(1,399)	43,330	(937)	139,993	(2,336)
Asset-backed securities	1,494	(3)	—	—	1,494	(3)
Total	\$ 196,489	\$ (2,151)	\$ 82,147	\$ (1,792)	\$ 278,636	\$ (3,943)

The Company reviewed its investment holdings as of June 30, 2023 and December 31, 2022 and determined that the decline in fair value is attributable to changes in interest rates and not credit quality, and as the Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. Therefore, there were no allowances for credit losses as of June 30, 2023 and December 31, 2022.

4. FAIR VALUE MEASUREMENTS

Investment Securities

The Company holds investment securities that consist of highly liquid, investment grade debt securities. The Company determines the fair value of its investment securities based upon one or more valuations reported by its investment accounting and reporting service provider. The investment service provider values the securities using a hierarchical security pricing model that relies primarily on valuations provided by an industry-recognized valuation service. Such valuations may be based on trade prices in active markets for identical assets or liabilities (Level 1 inputs) or valuation models using inputs that are observable either directly or indirectly (Level 2 inputs), such as quoted prices for similar assets or liabilities, yield curves, volatility factors, credit spreads, default rates, loss severity, current market and contractual prices for the underlying instruments or debt, and broker and dealer quotes, as well as other relevant economic measures.

Derivative Asset

On October 15, 2021, the Company received a warrant (the "Radionetics Warrant") to purchase the greater of 3,407,285 additional shares of common stock or the number of additional shares of common stock that would allow the Company to maintain an aggregate equity interest of 22% of the fully diluted capitalization of Radionetics. The estimated value of the Radionetics Warrant is based on valuations provided by a third-party valuation specialist using unobservable inputs due to little to no market data (Level 3 inputs). There were no material changes in the inputs or the total valuation of the Radionetics Warrant during the three and six months ended June 30, 2023.

Financial assets measured at fair value on a recurring basis as of June 30, 2023 and December 31, 2022 were as follows (*in thousands*):

	As of June 30, 2023			
	Level 1	Level 2	Level 3	Total
Investment securities:				
U.S. government and agency obligations	\$ 91,448	\$ 46,687	\$ —	\$ 138,135
Certificates of deposit	—	3,606	—	3,606
Corporate debt securities	—	75,704	—	75,704
Commercial paper	—	7,531	—	7,531
Total Investment securities	91,448	133,528	—	224,976
Derivative Assets:				
Radionetics Warrant	—	—	668	668
Total assets measured at fair value	\$ 91,448	\$ 133,528	\$ 668	\$ 225,644

	As of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Investment securities:				
U.S. government and agency obligations	\$ 93,879	\$ 58,851	\$ —	\$ 152,730
Certificates of deposit	—	4,535	—	4,535
Corporate debt securities	—	142,994	—	142,994
Asset-backed securities	—	1,494	—	1,494
Total Investment securities	93,879	207,874	—	301,753
Derivative Assets:				
Radionetics Warrant	—	—	668	668
Total assets measured at fair value	\$ 93,879	\$ 207,874	\$ 668	\$ 302,421

The Company's policy is to recognize transfers between levels of the fair value hierarchy on the date of the event or change in circumstances that caused the transfer. There were no transfers into or out of Level 3 during the six months ended June 30, 2023, or year ended December 31, 2022.

5. BALANCE SHEET DETAILS

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

	June 30, 2023	December 31, 2022
Prepaid clinical costs	\$ 3,933	\$ 2,567
Prepaid research and development costs	1,393	2,293
Australian tax incentive receivable	985	937
Prepaid insurance	372	939
Interest receivable	897	1,353
Due from Radionetics	97	135
Due from Sanwa	403	—
Landlord improvements receivable	9,440	605
Other	2,761	1,930
Total	\$ 20,281	\$ 10,759

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

	June 30, 2023	December 31, 2022
Leasehold improvements	\$ 3,516	\$ 3,516
Lab equipment	3,403	3,168
Office equipment	859	859
Computers and software	46	41
Property and equipment at cost	7,824	7,584
Less accumulated depreciation and amortization	(4,602)	(4,084)
Total	\$ 3,223	\$ 3,500

Accounts payable and accrued expenses consisted of the following (*in thousands*):

	June 30, 2023	December 31, 2022
Accounts payable	\$ 4,845	\$ 6,883
Accrued clinical costs	2,279	1,921
Accrued research and development costs	2,274	4,043
Accrued outside services and professional fees	2,234	1,810
Accrued landlord improvements	8,671	359
Other accrued expenses	522	335
Total	\$ 20,825	\$ 15,351

6. OPERATING LEASE

In February 2018, as amended in March 2018, the Company entered into a non-cancellable operating lease for a facility in San Diego, California (the "2018 Lease"). The 2018 Lease has an initial term of seven years which expires in August 2025, and the Company has an option to extend the term of the 2018 Lease for an additional five years, a termination option subject to early termination fees and an option to sublease the facility. The 2018 Lease is subject to base lease payments and additional charges for common area maintenance and other costs and includes certain lease incentives and tenant improvement allowances. The Company's estimated incremental fully collateralized borrowing rate of 8.0% was used in its present value calculation as the 2018 Lease does not have a stated rate and the implicit rate was not readily determinable.

In 2022, the Company entered into a lease agreement for laboratory and office space in San Diego, California (the "2022 Lease"). The Company expects to move its corporate headquarters to this new facility in the fourth quarter of 2023 upon the substantial completion of improvements.

Under the terms of the 2022 Lease, the Company's expected future monthly minimum lease payments of \$0.5 million, with six months of rent abatement in the first year, start on the earlier of (i) the date which is ten (10) months after substantial completion of demolition work, or (ii) the date of the substantial completion of improvements and first occupancy for business purposes, and the term expires on the date immediately preceding the one hundred thirty-seventh (137th) monthly anniversary of this lease payment start date. Lease payments are subject to annual 3% increases. The Company is also responsible for certain operating expenses and taxes during the term of the 2022 Lease. The 2022 Lease provides the Company with specified tenant improvement and landlord work allowances. The Company has (i) two options to extend the term of the 2022 Lease for an additional period of five (5) years each, and (ii) a right of first offer on adjacent space to the new facility, subject to the terms and conditions of the 2022 Lease. The lease will be measured and recognized upon lease commencement. As of June 30, 2023, the 2022 Lease did not commence because the construction of improvements to bring the facility to its intended use was ongoing and not substantially complete.

Under the terms of the 2018 Lease and 2022 Lease, the Company provided the lessors with irrevocable letters of credit in the amounts of \$0.5 million and \$0.8 million, respectively. The lessors are entitled to draw on the letters of credit in the event of any default by the Company under the terms of the leases.

As of June 30, 2023, the Company's future minimum payments under non-cancellable operating lease, were as follows (in thousands):

Year ending December 31,	Minimum Payments
2023 (6 months)	\$ 628
2024	1,280
2025	871
Total future minimum lease payments	2,779
Less imputed interest	(214)
Total operating lease liability	2,565
Less operating lease liability, current	(1,109)
Operating lease liability, non-current	\$ 1,456

Operating lease cost was \$0.3 million and \$0.6 million for the three and six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023 and December 31, 2022, the Company's 2018 Lease weighted average remaining term was 2.1 and 2.6 years, respectively. As of June 30, 2023 and December 31, 2022, the Company's weighted-average discount rate was 8%.

Cash paid for amounts included in the measurement of lease liabilities for operating cash flow from operating leases was \$0.3 million and \$0.6 million for the three and six months ended June 30, 2023 and 2022, respectively.

7. COMMITMENTS AND CONTINGENCIES

Litigation

From time to time, the Company may be subject to various claims and suits arising in the ordinary course of business. The Company does not expect that the resolution of these matters will have a material adverse effect on its financial position or results of operations.

8. REVENUE RECOGNITION

Sanwa Kagaku Kenkyusho Co., Ltd

On February 25, 2022, the Company and Sanwa Kagaku Kenkyusho Co., Ltd. ("Sanwa"), entered into a license agreement (the "Sanwa License") whereby the Company granted Sanwa an exclusive license to develop and commercialize paltusotine in Japan.

Under the Sanwa License, Sanwa has the right to receive data obtained by the Company through certain paltusotine studies. The Company assessed the Sanwa License and concluded that Sanwa is a customer within the agreement. Sanwa will assume all costs associated with clinical trials and regulatory applications associated with these processes in Japan. Further, the Company retains all

rights to develop and commercialize the product outside Japan. The Company also granted Sanwa the right to purchase supply of paltusotine for clinical and commercial requirements at cost plus a pre-negotiated percentage which was a market rate and therefore not a material right.

The Company determined that its performance obligations under the Sanwa License comprised the license and data exchange. Certain professional services, such as the Company's participation on committees, were deemed to be immaterial to the context of the contract.

In exchange, the Company received a \$13.0 million nonrefundable, upfront payment and will be eligible to receive up to an additional \$25.5 million in milestone payments related to the achievement of certain development, regulatory and commercial goals. In addition, upon market approval of paltusotine in Japan, the Company will be eligible to receive certain sales-based royalties. The Company determined that the transaction price amounted to the upfront payment of \$13.0 million. As there have been no sales to date, no sales-based milestones or royalties were recognized to date. Further, using the most-likely-method, the developmental milestone payments were considered fully constrained.

The control of the license was transferred to Sanwa at the inception of the contract and the Company does not have an ongoing performance obligation to support or maintain the licensed intellectual property. Revenue allocated to the data exchange obligation is recognized over time using the cost-to-cost measure as this method represents a faithful depiction of progress toward the ongoing paltusotine studies in the U.S. and related data transfer. Revenue is recognized on a gross basis as the Company is the principal.

Deferred revenue consisted of the following (*in thousands*):

	2023	2022
Deferred revenues as of January 1,	\$ 8,341	\$ —
Additions of deferred revenues	—	11,500
Revenue recognized that was included in deferred revenues	(1,189)	(2,069)
Balance as of June 30,	7,152	9,431
Less deferred revenue, current	(2,080)	(2,543)
Deferred revenue, non-current	<u>\$ 5,072</u>	<u>\$ 6,888</u>

During the three and six months ended June 30, 2023, \$0.6 million and \$1.2 million, respectively, of the \$13.0 million upfront payment was recognized as revenues in the accompanying condensed consolidated statements of operations and comprehensive loss. During the three and six months ended June 30, 2022, \$0.4 million and \$3.6 million, respectively, of the \$13.0 million upfront payment was recognized as revenues in the accompanying condensed consolidated statements of operations and comprehensive loss. Of the license revenues recognized during the six months ended June 30, 2022, \$1.5 million is related to the transfer of the license at the inception of the Sanwa License at a point in time, with the remaining amounts related to the data exchange performance obligation recognized over time. Deferred revenues are expected to be recognized over the duration of certain paltusotine studies conducted by the Company.

On June 14, 2022, the Company and Sanwa, entered into a clinical supply agreement (the "Sanwa Clinical Supply Agreement") whereby the Company is responsible for manufacturing and supplying certain materials to Sanwa for the completion of certain studies and trials under the Sanwa License. During each of the three and six months ended June 30, 2023, the Company recognized \$0.4 million of revenues from the Sanwa Clinical Supply Agreement in the accompanying condensed consolidated statements of operations and comprehensive loss. No significant supply purchases made by Sanwa through the Sanwa Clinical Supply Agreement during the three and six months ended June 30, 2022.

Cellular Longevity, Inc., doing business as Loyal

On March 24, 2023, the Company and Cellular Longevity Inc., doing business as Loyal ("Loyal") entered into a license agreement (the "Loyal License") whereby the Company granted Loyal an exclusive license to develop and commercialize CRN01941, a somatostatin receptor type 2 agonist, for veterinary use. In exchange the Company received a \$0.1 million nonrefundable, upfront payment and preferred stock in Loyal valued at approximately \$2.0 million. The Company will also be eligible to receive certain single-digit sales-based royalties if the licensed intellectual property is approved for veterinary use.

During the six months ended June 30, 2023, the Company recognized \$2.1 million of revenues from the Loyal License at the inception of the contract in the accompanying condensed consolidated statements of operations and comprehensive loss. As of June 30, 2023, the shares of Loyal preferred stock issued and to be issued to the Company valued at \$2.0 million is included in other assets in the accompanying condensed consolidated balance sheets. The Loyal preferred stock does not have a readily determinable fair value and is recorded at cost less impairment. The Company assesses equity securities without a readily determinable fair value for changes in observable prices each period, noting none.

9. STOCKHOLDERS' EQUITY

Stock Offerings

On April 18, 2022, the Company completed an underwritten follow-on offering of 5,625,563 shares of its common stock at a price to the public of \$22.22 per share. Net proceeds from the offering were approximately \$117.2 million, after underwriting discounts and commissions and estimated offering costs of approximately \$7.8 million. The shares were registered pursuant to the Company's 2021 Shelf Registration Statement.

Shelf Registration Statements and ATM Offering

On August 13, 2019, the Company filed a registration statement on Form S-3 (the "2019 Shelf Registration Statement"), covering the offering of up to \$300.0 million of common stock, preferred stock, debt securities, warrants and units. The 2019 Shelf Registration Statement became effective on August 29, 2019 and expired on August 29, 2022.

On August 13, 2019, the Company also entered into a Sales Agreement (the "Sales Agreement") with SVB Leerink LLC and Cantor Fitzgerald & Co. (collectively, the "Sales Agents"), under which the Company may, from time to time, sell shares of its common stock through the Sales Agents (the "ATM Offering"). The 2019 Shelf Registration Statement included a prospectus covering the offering, issuance, and sale of up to \$75.0 million of the Company's common stock from time to time through the ATM Offering.

Pursuant to the 2019 Shelf Registration Statement, the Company issued 275,764 shares of common stock in the ATM Offering for net proceeds of \$6.4 million, after deducting commissions. The Company did not issue any additional shares of common stock in the ATM Offering pursuant to the 2019 Shelf Registration Statement after the first quarter of 2020. The 2019 Shelf Registration Statement expired on August 29, 2022.

On August 10, 2021, the Company filed a registration statement on Form S-3 (the "2021 Shelf Registration Statement"), which became immediately effective upon filing, covering the offering of common stock, preferred stock, debt securities, warrants and units and the resale of up to 851,306 shares by the accredited investor who purchased shares in the Private Placement.

On August 12, 2022, the Company filed with the SEC a prospectus supplement, dated August 12, 2022, to the 2021 Shelf Registration Statement pursuant to Rule 424(b) under the Securities Act of 1933, as amended, relating to the offer and sale of up to \$150 million of shares of its common stock from time to time to or through the Sales Agents, pursuant to the Sales Agreement, in the ATM Offering. Following the expiration of the 2019 Shelf Registration Statement, the shares to be sold under the Sales Agreement may be issued and sold pursuant to the 2021 Shelf Registration Statement.

During the three and six months ended June 30, 2023, the Company issued 522,807 shares of common stock in the ATM Offering pursuant to the 2021 Shelf Registration Statement for net proceeds of approximately \$11.3 million, after deducting commissions.

10. EQUITY INCENTIVE PLANS

2021 Employment Inducement Incentive Award Plan

The Company adopted the 2021 Employment Inducement Incentive Award Plan (the "2021 Inducement Plan") in December 2021. The Company initially reserved 1,500,000 shares of the Company's common stock for issuance pursuant to awards granted under the 2021 Inducement Plan. The terms of the 2021 Inducement Plan are substantially similar to the terms of the Company's 2018 Incentive Award Plan with the exception that awards may only be made to an employee who has not previously been an employee or member of the board of directors of the Company if the award is in connection with commencement of employment. In 2022, the Company amended the 2021 Inducement Plan to increase the number of shares of the Company's common stock available for future issuance under the 2021 Inducement Plan to 5,000,000 shares. As of June 30, 2023, 1,240,434 shares of common stock were available for future issuance under the 2021 Inducement Plan.

2018 Incentive Award Plan

The Company adopted the 2018 Incentive Award Plan (the "2018 Plan") in July 2018. Under the 2018 Plan, which expires in July 2028, the Company may grant equity-based awards to individuals who are employees, officers, directors or consultants of the Company. Options issued under the 2018 Plan will generally expire ten years from the date of grant and vest over a four-year period. As of June 30, 2023, 2,510,587 shares of common stock were available for future issuance under the 2018 Plan.

The 2018 Plan contains a provision that allows annual increases in the number of shares available for issuance on the first day of each calendar year through January 1, 2028, in an amount equal to the lesser of: (i) 5% of the aggregate number of shares of the Company's common stock outstanding on December 31 of the immediately preceding calendar year, or (ii) such lesser amount determined by the Company. Under this evergreen provision, on January 1, 2023, an additional 2,693,859 shares became available for future issuance under the 2018 Plan.

2015 Stock Incentive Plan

The Company adopted the 2015 Stock Incentive Plan (the "2015 Plan") in February 2015, which provided for the issuance of equity awards to the Company's employees, members of its board of directors and consultants. In general, options issued under this plan vest

over four years and expire after 10 years. Subsequent to the adoption of the 2018 Plan, no additional equity awards can be made under the 2015 Plan.

2018 Employee Stock Purchase Plan

The Company adopted the 2018 Employee Stock Purchase Plan (the “ESPP”) in July 2018. The ESPP permits participants to purchase common stock through payroll deductions of up to 20% of their eligible compensation. As of June 30, 2023, 1,664,012 shares of common stock were available for issuance under the ESPP.

The ESPP contains a provision that allows annual increases in the number of shares available for issuance on the first day of each calendar year through January 1, 2028, in an amount equal to the lesser of: (i) 1% of the aggregate number of shares of the Company’s common stock outstanding on December 31 of the immediately preceding calendar year, or (ii) such lesser amount determined by the Company. Under this evergreen provision, on January 1, 2023, an additional 538,771 shares became available for future issuance under the ESPP.

Stock Awards

Stock Options

Activity under the Company’s stock option plans during the six months ended June 30, 2023 was as follows:

	Options Outstanding	Weighted- Average Exercise Price	Weighted- Average Remaining Term	Aggregate Intrinsic Value (000's)
Balance on December 31, 2022	9,757,329	\$ 17.79		
Granted	3,232,590	\$ 19.62		
Exercised	(125,866)	\$ 14.55		
Forfeited and expired	(441,039)	\$ 21.54		
Balance on June 30, 2023	<u>12,423,014</u>	\$ 18.16	8.1	\$ 22,275
Vested and expected to vest on June 30, 2023	<u>12,423,014</u>	\$ 18.16	8.1	\$ 22,275
Exercisable on June 30, 2023	<u>5,091,163</u>	\$ 16.63	6.8	\$ 18,069

Aggregate intrinsic value is calculated as the difference at a specific point in time between the closing price of the Company’s common stock and the exercise price of stock options that had exercise prices below the closing price. The aggregate intrinsic value of options exercised during the six months ended June 30, 2023 and 2022 was \$0.8 million and \$5.1 million, respectively.

Restricted Stock Units

The Company’s restricted stock unit activity during the six months ended June 30, 2023, was as follows:

	Restricted Stock Units Outstanding	Weighted- Average Grant Date Fair Value
Balance on December 31, 2022	290,311	\$ 19.88
Granted	646,621	\$ 19.68
Vested	(81,294)	\$ 19.54
Forfeited	(12,543)	\$ 19.78
Balance on June 30, 2023	<u>843,095</u>	\$ 19.77

Fair Value of Stock Awards

The Company estimates the fair value of all stock option grants and the ESPP using the Black-Scholes option pricing model and recognizes forfeitures as they occur. The following table summarizes the weighted average assumptions used to estimate the fair value of stock options granted under the Company’s stock option plans for the periods presented below:

Stock Option Awards	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Expected option term	6.0 years	6.1 years	6.0 years	6.0 years
Expected volatility	65%	87%	66%	88%
Risk free interest rate	3.6%	2.9%	4.0%	2.2%
Expected dividend yield	—%	—%	—%	—%

The weighted-average fair value of stock options awarded was \$12.56 and \$12.38 per share during the three and six months ended June 30, 2023, respectively, and \$15.50 and \$15.02 per share during the three and six months ended June 30, 2022, respectively.

The following table summarizes the weighted average assumptions used to estimate the fair value of the ESPP for the periods presented below:

ESPP	Three and six months ended June 30,	
	2023	2022
Expected term	1.1 years	1.2 years
Expected volatility	57%	76%
Risk free interest rate	4.9%	2.2%
Expected dividend yield	—%	—%

The weighted-average fair value of the ESPP was \$9.15 per share during each of the three and six months ended June 30, 2023, respectively, and \$8.82 per share during each of the three and six months ended June 30, 2022, respectively.

The key assumptions used in determining the fair value of equity awards, and the Company's rationale, were as follows: (i) Expected term - the expected term for stock options represents the period that the stock options are expected to be outstanding and has been estimated using the simplified method, which is an average of the contractual option term and its vesting period; the expected term for awards granted under the ESPP represents the term the awards are expected to be outstanding; (ii) Expected volatility - during 2022, the expected volatility assumption was based on volatilities of a peer group of similar companies in the biotechnology industry whose share prices are publicly available. The Company computed the historical volatility data using the daily closing prices for the selected companies' shares during the period equivalent to the expected term of the Company's stock-based awards. Beginning in 2023, the Company determined that the volatility of its own market-traded shares best represents the expected volatility based on available historical data and, therefore, the expected volatility assumption for stock-based awards granted during the three and six months ended June 30, 2023 is based on the historical volatility of the Company's common stock; (iii) Risk-free interest rate - the risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities that approximate the expected terms of awards; and (iv) Expected dividend yield - the expected dividend yield assumption is zero as the Company has never paid dividends and has no present intention to do so in the future.

Restricted stock units are valued using the grant date stock price.

Stock-Based Compensation Expense

Stock-based compensation expense for the equity awards issued by the Company to employees and non-employees for the periods presented below was as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Included in research and development	\$ 5,602	\$ 3,681	\$ 10,280	\$ 6,872
Included in general and administrative	4,573	3,450	7,991	6,014
Total stock-based compensation expense	<u>\$ 10,175</u>	<u>\$ 7,131</u>	<u>\$ 18,271</u>	<u>\$ 12,886</u>

As of June 30, 2023, unrecognized stock-based compensation cost related to option awards, restricted stock units, and ESPP was \$92.4 million, \$15.2 million and 2.8 million, respectively, which is expected to be recognized over a remaining weighted-average period of 2.2 years, 3.5 years and 1.4 years, respectively.

10. SUBSEQUENT EVENTS

In August 2023, the Company exercised its warrant to purchase 3,407,285 shares of Radionetics common stock with an exercise price of \$0.00001 and invested \$5.0 million to purchase 14,404,656 shares of preferred stock in Radionetics along with other new and existing investors who participated in the financing. Subsequent to the warrant exercise, the Company exchanged 60% of its total number of outstanding shares of Radionetics common stock into 32,344,371 shares of Radionetics preferred stock. Following these transactions, the Company owns approximately 63% of Radionetics common stock and 25% of Radionetics preferred stock. Additionally, the Collaboration and License Agreement between Crinetics and Radionetics, dated October 15, 2021, was amended to include additional sales milestones of up to \$15 million.

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

You should read the following discussion of our financial condition and results of operations in conjunction with the unaudited condensed consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2022.

Forward Looking Statements

The following discussion and other parts of this quarterly report contain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this quarterly report, including statements regarding our future results of operations and financial position, business strategy, the impact of the COVID-19 pandemic, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. The forward-looking statements in this quarterly report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, operating results, business strategy, short-term and long-term business operations and objectives. These forward-looking statements speak only as of the date of this quarterly report and are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A, "Risk Factors." The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Overview

We are a clinical-stage pharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for endocrine diseases and endocrine-related tumors. Endocrine pathways function to maintain homeostasis and commonly use peptide hormones acting through G protein coupled receptors, or GPCRs, to regulate many aspects of physiology including growth, energy, metabolism, gastrointestinal function and stress responses. We have built a highly productive drug discovery and development organization with extensive expertise in endocrine GPCRs. We have discovered a pipeline of oral nonpeptide (small molecule) new chemical entities that target peptide GPCRs to treat a variety of rare endocrine diseases where treatment options have significant efficacy, safety and/or tolerability limitations. Our product candidates include paltusotine (formerly CRN00808), which is in clinical development for the treatment of acromegaly and neuroendocrine tumors complicated by carcinoid syndrome, and CRN04894, which is in clinical development for diseases of excess adrenocorticotrophic hormone, or ACTH, including Cushing's disease and congenital adrenal hyperplasia, or CAH. We are advancing additional product candidates through preclinical discovery and development studies in parallel. Our vision is to build the leading endocrine company which consistently pioneers new therapeutics to help patients better control their disease and improve their daily lives.

We focus on the discovery and development of oral nonpeptide therapeutics that target peptide GPCRs with well understood biological functions, validated biomarkers and the potential to substantially improve the treatment of endocrine diseases and/or endocrine-related tumors. Our pipeline consists of the following product candidates:

Paltusotine (SST2 Agonist Program)

Paltusotine, our lead product candidate, establishes a new class of oral selective nonpeptide somatostatin receptor type 2, or SST2, agonists designed for the treatment of acromegaly and neuroendocrine tumors, or NETs. Somatostatin is a neuropeptide hormone that broadly inhibits the secretion of other hormones, including growth hormone, or GH, from the pituitary gland. Acromegaly arises from a benign pituitary tumor that secretes excess GH that, in turn, causes excess secretion of insulin-like growth factor-1, or IGF-1, by the liver. This loss of homeostasis in the GH axis results in excess tissue growth and other adverse metabolic effects throughout the body. Approximately 27,000 people in the United States suffer from acromegaly, and depending on surgical success, we estimate that approximately 11,000 are candidates for chronic pharmacological intervention, of which somatostatin peptide analogs are the primary pharmacotherapy. NETs originate from neuroendocrine cells commonly found in the gut, lung or pancreas. Typically, NETs are only diagnosed at a time of extensive metastatic disease and will often progress to liver failure. NETs are present in approximately 175,000 adults in the United States. Of these, it is estimated that approximately 33,000 patients have carcinoid syndrome, which occurs when the tumors secrete hormones or other chemical substances into the bloodstream that cause severe flushing or diarrhea, among other symptoms. Most NETs overexpress SST2 receptors and injected depots of peptide somatostatin analogs have become the first-line standard of care for many NETs patients as detailed in National Comprehensive Cancer Network, or NCCN, guidelines. In 2022, branded somatostatin peptide drugs accounted for approximately \$2.8 billion in global sales for the treatment of acromegaly, NETs and other uses. These drugs require painful monthly or daily injections and, in the case of somatostatin peptide drugs, often fail to fully control the disease in many acromegaly patients. The U.S. Food and Drug Administration, or FDA, has granted orphan drug designation for paltusotine for the treatment of acromegaly.

To date, we have conducted multiple Phase 1 and Phase 2 clinical trials and results have shown that paltusotine was generally well tolerated among healthy adults and patients with acromegaly. In our ACROBAT Phase 2 program in acromegaly patients, including in our ACROBAT Advance long-term extension study, paltusotine maintained IGF-1 levels in patients previously treated with injected somatostatin receptor ligands, or SRLs, in which paltusotine lowered and maintained IGF-1 for up to 103 weeks at levels comparable to prior injected SRL therapy.

We are currently conducting a Phase 3 development program for paltusotine in acromegaly which consists of two placebo-controlled clinical trials. The first of these, the PATHFNDR-1 trial, is designed as a double-blind, placebo-controlled, nine-month clinical trial of paltusotine in acromegaly patients with average IGF-1 levels less than or equal to 1.0 times the upper limit of normal, or ULN, and who are on stable doses of somatostatin receptor ligand monotherapy (octreotide LAR or lanreotide depot). We are also conducting a second study, the PATHFNDR-2 trial, which is designed as a double-blind, placebo-controlled, six-month clinical trial of acromegaly patients with elevated IGF-1 levels who are untreated. Three groups of subjects have been enrolled in PATHFNDR-2, including subjects who are treatment-naïve (Group 1), subjects are not receiving medical therapy and who last received medical therapy at least four months prior to screening (Group 2), and subjects who are controlled on octreotide or lanreotide but agree to washout prior to beginning study treatment (Group 3). Groups 1 and 2 constitute Stratum 1 and Group 3 constitutes Stratum 2. The PATHFNDR-2 study population was stratified to ensure equivalent active treatment versus placebo allocations in each stratum. We originally planned to enroll approximately 76 subjects based on the assumption that there would be an equal number of subjects in each stratum. Due to higher than expected enrollment of naïve patients, we increased the targeted sample size to 98 patients in order to ensure sufficient statistical power to detect a difference between the active and placebo groups for the study as a whole and to increase experience with paltusotine in naïve and untreated patients. The sample size adjustment was prespecified in the protocol if enrollment in Stratum 2 was below a predetermined threshold. The primary endpoint of both PATHFNDR studies is the proportion of patients with $IGF-1 \leq 1.0 \times ULN$ at the end of the treatment period on paltusotine as compared to placebo. Enrollment in PATHFNDR-1 was completed in 2022, and we expect topline data from the PATHFNDR-1 study in September 2023. Enrollment in the PATHFNDR-2 study was completed in August 2023 and a total of 112 subjects were enrolled who were either treatment-naïve (n=46) or untreated for at least four months (n=36), or who washed out of prior octreotide or lanreotide monotherapy (n=30). We expect topline data from the PATHFNDR-2 study in the first quarter of 2024. We believe that, if successful, the two trials could support marketing applications for the use of paltusotine for all acromegaly patients who require pharmacotherapy, including untreated patients and those switching from other therapies, and we would plan to seek regulatory approval for paltusotine for the treatment of acromegaly in the United States with an anticipated submission of a New Drug Application, or NDA, in 2024.

We are also conducting a Phase 2 trial to assess the safety and pharmacokinetics of paltusotine in patients with NETs complicated by carcinoid syndrome. The primary objectives for this Phase 2 trial include the evaluation of safety, tolerability, and pharmacokinetics of multiple doses of paltusotine. In addition, exploratory efficacy during the 8-week period will be evaluated including frequency of bowel movements and flushing episodes. We expect preliminary data from this study in the fourth quarter of 2023.

In February 2022, we entered into a license agreement with Sanwa Kagaku Kenkyusho Co., Ltd., or Sanwa, pursuant to which Sanwa has the exclusive right to develop and commercialize paltusotine in Japan, or the Sanwa License.

CRN04894 (ACTH Antagonist)

CRN04894 is our investigational, oral, nonpeptide product candidate designed to antagonize the ACTH receptor, intended for the treatment of diseases caused by excess ACTH, including Cushing's disease and CAH. Cushing's disease results from a pituitary tumor that secretes excess ACTH which, in turn, causes the downstream synthesis and over-secretion of cortisol by the adrenal glands. Cortisol is the body's main stress hormone and excess amounts can cause significant increases in mortality and morbidity. CAH encompasses a set of disorders that are caused by genetic mutations that result in impaired cortisol synthesis. A lack of cortisol leads to a loss of feedback mechanisms and results in persistently high levels of ACTH, which, in turn, causes overstimulation of the adrenal cortex. The resulting adrenal hyperplasia and over-secretion of other steroids (particularly androgens) and steroid precursors can lead to a variety of effects from improper gonadal development to life-threatening dysregulation of mineralocorticoids. In the United States, there are an estimated 27,000 patients with CAH and over 11,000 patients with Cushing's disease. Of the patients with CAH and Cushing's disease, we estimate that 17,000 and 5,000 patients, respectively, are potential candidates for treatment with CRN04894.

We conducted a double-blind, randomized, placebo-controlled Phase 1 study of CRN04894 in healthy volunteers to assess the safety and tolerability of single and multiple doses of CRN04894. In addition, the study was designed to measure the effect of CRN04894 on suppression of cortisol, cortisol precursors, and adrenal androgens following exogenous ACTH stimulation. We announced positive topline data from the Phase 1 study. CRN04894 was well tolerated and demonstrated dose-dependent increases in CRN04894 plasma concentrations. We believe CRN04894 demonstrated pharmacologic proof-of-concept, as the Phase 1 results showed reductions of both basal cortisol and elevated cortisol following an ACTH challenge. All adverse events were considered mild to moderate and there were no serious adverse events.

In the fourth quarter of 2022, we entered into a Clinical Trial Agreement with the National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, of the National Institutes of Health, or NIH, to collaborate on a company-sponsored multiple-ascending dose exploratory trial of CRN04894 in ACTH dependent Cushing's Syndrome, or ADCS. ADCS includes patients with either

Cushing's disease or Ectopic ACTH Syndrome, or EAS. This open-label study is designed to evaluate safety and pharmacokinetics of increasing doses of CRN04894 in patients with ADCS as well as to measure 24-hour urinary-free cortisol and serum cortisol as indicators of efficacy. Study activities have been initiated and, based on our current projections data is expected from the study in 2024.

In January 2023, we submitted an Investigational New Drug application, or IND, to the FDA for the study of CRN04894 in CAH. In February 2023, we were notified that the IND was allowed to proceed, and we initiated a Phase 2 study in CAH patients. This open-label Phase 2 study is designed to evaluate the safety and pharmacokinetics of increasing doses of CRN04894. In addition, biomarkers, including serum androstenedione and 17 hydroxyprogesterone, will be measured as we seek to evaluate the potential efficacy of CRN04894. Data from this Phase 2 study is expected in 2024.

CRN04777 (SST5 Agonist)

CRN04777 is our investigational, oral, nonpeptide somatostatin receptor type 5, or SST5, agonist designed for the treatment of congenital hyperinsulinism, or HI. Congenital HI is a devastating rare genetic disease associated with dysregulated insulin production, in which excess insulin produces life-threatening hypoglycemia (low blood glucose) beginning at birth. This loss of homeostatic control of blood glucose levels can lead to seizures, developmental disorders, learning disabilities, coma and even death. Congenital HI occurs in approximately 1 in 25,000 to 50,000 new births in the United States. Approximately 2,200 patients in the United States are diagnosed with Congenital HI, and depending on surgical success, we estimate that approximately 1,500 are candidates for chronic pharmacological intervention. We completed a double-blind, randomized, placebo-controlled Phase 1 study of CRN04777 in healthy volunteers to assess the safety and tolerability of single and multiple doses of CRN04777. In addition, the study was designed to evaluate the potential mechanism of action of CRN04777 by measuring the suppression of insulin secretion in healthy volunteers following stimulation with either glucose or a sulfonylurea, agents that increase the secretion of insulin. We announced positive topline data from the single ascending dose, or SAD, cohorts and the multiple ascending dose, or MAD, cohorts and we believe CRN04777 demonstrated pharmacologic proof-of-concept, based on potent suppression of stimulated insulin observed in these subjects. The plasma exposure of CRN04777 suggested the drug was well absorbed with a half-life of approximately 40 hours, which we believe supports the potential for once daily administration in patients. All adverse events were considered mild or moderate and there were no serious adverse events. CRN04777 was well tolerated at single and multiple doses from 0.5 mg up to 120 mg and exhibited dose-proportional pharmacokinetics for the same dose range. A dose-dependent reduction in glucose-induced insulin secretion was demonstrated with an intravenous glucose tolerance test in the SAD cohorts and a dose-dependent reversal of sulfonylurea-induced insulin secretion was seen in both the SAD and MAD cohorts. The sulfonylurea-induced insulin secretion model represents a pharmacologic analog of the hyperinsulinism that many patients experience.

Following the completion of the adult healthy volunteer study under a Clinical Trial Application in Germany, we submitted an IND to the FDA in October 2022 to initiate the first U.S. clinical study of CRN04777, which is designed to evaluate the compound in a pediatric population (ages 3 months to 12 years). In November 2022, the FDA informed us that the IND was placed on clinical hold and the proposed Phase 2 clinical study was not able to be initiated. Since the receipt of the clinical hold, we have conducted additional toxicology studies to continue the nonclinical evaluation of CRN04777. While developing our response to the clinical hold issued by the FDA, results from additional nonclinical studies became available. These studies uncovered findings at exposure levels that eroded anticipated therapeutic margins for CRN04777. These other findings are not related to those originally cited by the FDA for the clinical hold and are not present in nonclinical studies that have been conducted with other Crinetics product candidates under development. We believe them to be specific to CRN04777 and not associated with its somatostatin receptor type 5 (SST5) mechanism of action. In light of these findings, we have decided to suspend further significant investment in CRN04777 at this time. Crinetics plans to evaluate the potential development of earlier stage compounds that target the SST5 receptor for the treatment of congenital hyperinsulinism.

Parathyroid Hormone Antagonist

We are developing antagonists of the parathyroid hormone, or PTH, receptor for the treatment of primary hyperparathyroidism, or PHPT and humoral hypercalcemia of malignancy, or HHM, and other diseases of excess PTH. PTH regulates calcium and phosphate homeostasis in bone and kidney through activation of its receptor, PTHR1. Increased activation of PTHR1, either via PTH or PTH-related peptide (PTHrP, PTHLH) can lead to skeletal, renal, gastrointestinal, and neurological problems. Primary hyperparathyroidism arises from a small, benign tumor on one or more of the parathyroid glands, which results in over-secretion of PTH, leading to increased blood calcium levels, or hypercalcemia. Some patients experience no symptoms, and many can have surgery to remove the tumor and/or hyperactive gland(s), while some require management with medical therapy. Symptomatic PHPT is characterized by skeletal, renal, gastrointestinal, and neurological manifestations with increased mortality. HHM typically arises in patients with advanced-stage cancers. In cases of HHM, over-secretion of PTHrP caused by the malignant tumor results in bone resorption and calcium reabsorption in the kidney, leading to hypercalcemia. We have identified investigational, orally available nonpeptide PTH antagonists that showed activity and drug-like properties in preclinical models. We are evaluating a subset of molecules to identify potential development candidates that we believe are suitable for evaluation in human clinical trials, and we expect to select a development candidate in 2023.

Treatment for Autosomal Dominant Polycystic Kidney Disease

We are developing nonpeptides for the treatment of primary Autosomal Dominant Polycystic Kidney Disease, or ADPKD. ADPKD develops because of mutations in either the PKD1 or PKD2 genes and is the most common hereditary kidney disease, affecting approximately 1 in 1000 individuals, and is the fourth leading cause of End Stage Renal Disease, or ESRD. These mutations lead to bilateral cyst formation and progressive decline in a patient's Glomerular Filtration Rate, or GFR, ultimately leading to kidney failure in 50% of individuals by their sixth decade with the disease. We have identified investigational, orally available nonpeptide molecules that possess good drug-like properties and activity in preclinical models of ADPKD. We are evaluating a subset of these molecules to identify potential development candidates that we believe are suitable for evaluation in human clinical trials, and we expect to select a development candidate in 2023.

Radionetics Oncology, Inc.

On October 18, 2021, we, together with 5AM Ventures and Frazier Healthcare Partners, announced the formation of Radionetics Oncology, Inc., or Radionetics. Radionetics aims to develop a deep pipeline of novel, targeted, nonpeptide radiopharmaceuticals for the treatment of a broad range of oncology indications. In connection with the formation of Radionetics, we entered into a Collaboration and License Agreement with Radionetics, or the Radionetics License, granting Radionetics an exclusive world-wide license to our technology for the development of radiotherapeutics and related radio-imaging agents in exchange for a majority equity stake in Radionetics, a warrant to obtain additional shares of common stock of Radionetics, potential sales milestones in excess of \$1.0 billion and single-digit royalties on net sales. In August 2023, we exercised our warrant to purchase 3,407,285 shares of Radionetics common stock with an exercise price of \$0.00001 and invested \$5.0 million to purchase 14,404,656 shares of preferred stock in Radionetics along with new and existing investors who participated in the financing. Subsequent to the warrant exercise, we exchanged 60% of our total number of outstanding shares of Radionetics common stock into 32,344,371 shares of Radionetics preferred stock. Following these transactions, we own approximately 63% of Radionetics common stock and 25% of Radionetics preferred stock. Additionally, the Collaboration and License Agreement between Crinetics and Radionetics, dated October 15, 2021, was amended to include additional sales milestones of up to \$15 million. Following the amendment to the Collaboration and License Agreement, we are eligible to receive total potential sales milestones in excess of \$1.0 billion and single-digit royalties on net sales.

Research Discovery

Patients with many other debilitating endocrine diseases await new therapeutic options, and we are continuously evaluating where to next deploy our drug discovery efforts. We plan to continue to expand our drug discovery efforts and leverage our expertise in the evaluation of additional conditions including metabolic diseases (including diabetes and obesity) and Graves' Disease (including Thyroid Eye Disease), among other indications. All of our product candidates have been discovered, characterized and developed internally and are the subject of composition of matter patent applications. We do not have any royalty obligations and have retained worldwide rights to commercialize our product candidates, except with respect to the exclusive right to develop and commercialize paltusotine in Japan pursuant to the Sanwa License, and the exclusive right to our radiotherapeutics technology pursuant to the Radionetics License.

Australian operations

In January 2017, we established Crinetics Australia Pty Ltd, or CAPL, a wholly-owned subsidiary which was formed to conduct various preclinical and clinical activities for our product and development candidates. We believe CAPL will be eligible for certain financial incentives made available by the Australian government for research and development expenses. Specifically, the Australian Taxation Office provides for a refundable tax credit in the form of a cash refund equal to 43.5% of qualified research and development expenditures under the Australian Research and Development Tax Incentive Program, or the Australian Tax Incentive, to Australian companies that operate the majority of their research and development activities associated with such projects in Australia. A wholly-owned Australian subsidiary of a non-Australian parent company is eligible to receive the refundable tax credit, provided that the Australian subsidiary retains the rights to the data and intellectual property generated in Australia, and provided that the total revenues of the parent company and its consolidated subsidiaries during the period for which the refundable tax credit is claimed are less than \$20.0 million Australian dollars. If we lose our ability to operate CAPL in Australia, or if we are ineligible or unable to receive the research and development tax credit, or the Australian government significantly reduces or eliminates the tax credit, the actual refund amounts we receive may differ from our estimates.

COVID-19

As we continue to actively advance our programs, we are in close contact with our principal investigators and clinical sites and continue to assess any impacts of the COVID-19 global pandemic on our drug manufacturing, nonclinical activities, and clinical trials, expected timelines, and costs on an ongoing basis. The direct and indirect impacts of COVID-19 on our business could alter our forecasted timelines. We will continue to evaluate the impact of the COVID-19 pandemic on our business.

Financial operations overview

To date, we have devoted substantially all of our resources to drug discovery, conducting preclinical studies and clinical trials, obtaining and maintaining patents related to our product candidates, licensing activities, and the provision of general and administrative support for these operations. We have recognized revenues from various research and development grants and license and collaboration agreements, but do not have any products approved for sale and have not generated any product sales. We have funded our operations primarily through our grant and license revenues, the private placement of our preferred stock, and sales of our common stock. As of June 30, 2023, we had unrestricted cash, cash equivalents, and investment securities of \$264.5 million.

We have incurred cumulative net losses since our inception and, as of June 30, 2023, we had an accumulated deficit of \$536.1 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and preclinical studies and our expenditures on other research and development activities. We expect our expenses and operating losses will increase substantially as we conduct our ongoing and planned clinical trials, continue our research and development activities and conduct preclinical studies, hire additional personnel, protect our intellectual property and incur costs associated with being a public company, including audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission, or SEC, requirements, director and officer insurance premiums, and investor relations costs.

We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially, collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, scale back or discontinue the development of our existing product candidates or our efforts to expand our product pipeline.

Revenues

To date, our revenue has been mainly derived from research grant awards and licenses. As our data exchange performance obligation under the Sanwa License is fulfilled, we expect to recognize as revenues the deferred revenue amounts included in the accompanying condensed consolidated balance sheets as of June 30, 2023. We will recognize royalty and milestone revenues under our license agreements if and when appropriate under the relevant accounting rules (see Note 8 to our condensed consolidated financial statements). We have not generated any revenues from the commercial sale of approved products, and we do not expect to generate revenues from the commercial sale of our product candidates for at least the foreseeable future, if ever.

License revenues

License revenues for 2022 were primarily derived from the Sanwa License, under which Sanwa was granted the exclusive right to develop and commercialize paltusotine in Japan.

On March 24, 2023, we and Cellular Longevity Inc., doing business as Loyal ("Loyal") entered into a license agreement (the "Loyal License") pursuant to which we granted Loyal an exclusive license to develop and commercialize CRN01941, a somatostatin receptor type 2 agonist, for veterinary use.

License revenues for 2023 were primarily derived from the Sanwa License and the Loyal License.

Clinical supply revenues

On June 14, 2022, we and Sanwa, entered into a clinical supply agreement, or the Sanwa Clinical Supply Agreement, whereby we are responsible for manufacturing and supplying certain materials to Sanwa for specified activities under the Sanwa License. During each of the three and six months ended June 30, 2023, we recognized \$0.4 million of revenues from the Sanwa Clinical Supply Agreement in the accompanying condensed consolidated statements of operations and comprehensive loss. No significant supply purchases were made by Sanwa through the Sanwa Clinical Supply Agreement during the three and six months ended June 30, 2022.

Research and development

To date, our research and development expenses have related primarily to discovery efforts and preclinical and clinical development of our product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Research and development expenses include:

- salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in research and development efforts;
- external research and development expenses incurred under agreements with contract research organizations, or CROs, investigative sites and consultants to conduct our clinical trials and preclinical and nonclinical studies;

- costs related to manufacturing our product candidates for clinical trials and preclinical studies, including fees paid to third-party manufacturers;
- costs related to compliance with regulatory requirements;
- laboratory supplies; and
- facilities, depreciation and other allocated expenses for rent, facilities maintenance, insurance, equipment and other supplies.

We recognize the Australian Tax Incentive as a reduction of research and development expense. The amounts are determined based on eligible research and development expenditures. The Australian Tax Incentive is recognized when there is reasonable assurance that the Australian Tax Incentive will be received, the relevant expenditure has been incurred, and the amount of the Australian Tax Incentive can be reliably measured.

Our direct research and development expenses consist principally of external costs, such as fees paid to CROs, investigative sites and consultants in connection with our clinical trials, preclinical and non-clinical studies, and costs related to manufacturing clinical trial materials. The majority of our third-party expenses during 2023 and 2022 related to the research and development of paltusotine, CRN04894, and CRN04777. We deploy our personnel and facility related resources across all of our research and development activities.

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

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- number of doses that patients receive;
- drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates; and
- the efficacy and safety profile of our product candidates.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of our product candidates and the discovery of new product candidates. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. We will need to raise substantial additional capital in the future. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

General and administrative

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for personnel in executive, finance and other administrative functions. Other significant costs include facility-related costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services, insurance costs, and commercial planning expenses. We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities and, if any of our product candidates receive marketing approval, commercialization activities. We also incur expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs associated with operating as a public company.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities at the date of our condensed consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances at the time the estimates are made, the results of which form the basis for making judgments about the book values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies are those accounting principles generally accepted in the United States that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. For a description of our critical accounting policies, please see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Estimates" contained in our Annual Report on Form 10-K for the year ended December 31, 2022.

Other than those changes discussed below in the section entitled "Stock-based compensation expense", during the three and six months ended June 30, 2023, there have not been any material changes to the critical accounting estimates discussed therein.

Stock-based compensation expense

Beginning in the first quarter of 2023, we determined that the volatility of our own market-traded shares best represents the expected volatility based on the available historical data and, therefore, the expected volatility assumption used to value certain stock-based awards granted during the three and six months ended June 30, 2023 utilizes the historical volatility of our common stock. Previously, the expected volatility assumption used in the Black-Scholes option pricing model for certain stock-based awards was based on volatilities of a peer group of similar companies in the biotechnology industry whose share prices were publicly available. We calculated the historical volatility using the daily closing prices for the selected companies' shares during the period equivalent to that of the expected term of our stock-based awards.

Results of Operations

Comparison of the three months ended June 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended June 30, 2023 and 2022 (*in thousands*):

	Three months ended June 30,		Dollar Change
	2023	2022	
Revenues	\$ 988	\$ 439	\$ 549
Operating expenses:			
Research and development	40,640	32,995	7,645
General and administrative	13,343	10,489	2,854
Total operating expenses	53,983	43,484	10,499
Loss from operations	(52,995)	(43,045)	(9,950)
Other income, net	2,016	670	1,346
Net loss	<u>\$ (50,979)</u>	<u>\$ (42,375)</u>	<u>\$ (8,604)</u>

Revenues. Revenues during the three months ended June 30, 2023 and 2022 primarily relate to the Sanwa License and the Sanwa Clinical Supply Agreement.

Research and development expenses. Research and development expenses were \$40.6 million and \$33.0 million for the three months ended June 30, 2023 and 2022, respectively. The change was primarily due to an increase in personnel costs of \$6.9 million, increased consulting and outside services of \$1.6 million, increased other expenditures of \$0.7 million, partially offset by decreased net spending on manufacturing and development activities of \$1.6 million associated with our clinical and nonclinical programs.

The following table summarizes our primary external and internal research and development expenses for the three months ended June 30, 2023 and 2022 (in thousands):

	Three months ended June 30,		Dollar Change
	2023	2022	
External research and development expenses:			
Clinical trials	\$ 9,450	\$ 10,601	\$ (1,151)
Contract manufacturing	3,133	4,815	(1,682)
Preclinical studies	4,320	3,117	1,203
Outside services	3,587	2,023	1,564
Other external research and development	17	35	(18)
Total external research and development expenses	20,507	20,591	(84)
Internal expenses:			
Payroll and benefits	12,436	7,466	4,970
Stock-based compensation	5,602	3,681	1,921
Facilities and related	858	696	162
Other internal research and development	1,237	561	676
Total internal research and development expenses	20,133	12,404	7,729
Total research and development expenses	\$ 40,640	\$ 32,995	\$ 7,645

The following table summarizes our research and development expenses by program for the three months ended June 30, 2023 and 2022 (in thousands):

	Three months ended June 30,		Dollar Change
	2023	2022	
Paltusotine	\$ 10,124	\$ 12,271	\$ (2,147)
CRN04894	3,503	2,361	1,142
CRN04777	2,719	2,861	(142)
Discovery	3,553	1,961	1,592
Payroll and benefits	12,436	7,466	4,970
Stock-based compensation	5,602	3,681	1,921
Other	2,703	2,394	309
Total research and development expenses	\$ 40,640	\$ 32,995	\$ 7,645

Research and development expenses for our paltusotine program were \$10.1 million and \$12.3 million for the three months ended June 30, 2023 and 2022, respectively. The change was primarily due to decreased spending on manufacturing and development activities with our clinical and nonclinical activities of \$2.8 million partially offset by an increase in consulting and outside services of \$0.6 million.

Research and development expenses for our CRN04894 program were \$3.5 million and \$2.4 million for the three months ended June 30, 2023 and 2022, respectively. The change was primarily due to increased spending on manufacturing and development activities with our clinical and nonclinical activities of \$1.1 million.

Research and development expenses for our CRN04777 program were \$2.7 million and \$2.9 million for the three months ended June 30, 2023 and 2022, respectively. The change was primarily due to a decrease in consulting and outside services of \$0.2 million partially offset by increased spending on manufacturing and development activities with our clinical and nonclinical activities of \$0.1 million.

Research and development expenses for our discovery programs were \$3.6 million and \$2.0 million for the three months ended June 30, 2023 and 2022, respectively. The change was primarily due to an increase in consulting and outside services of \$1.4 million.

Research and development expenses for payroll and benefits were \$12.4 million and \$7.5 million for the three months ended June 30, 2023 and 2022, respectively. The change was primarily due to an increase in headcount to support our ongoing programs.

Research and development expenses for stock-based compensation were \$5.6 million and \$3.7 million for the three months ended June 30, 2023 and 2022, respectively. The change was primarily due to an increase in headcount to support our ongoing programs.

Research and development expenses for our other programs were \$2.7 million and \$2.4 million for the three months ended June 30, 2023 and 2022, respectively. The change was primarily due to an increase in other expenditures of \$0.4 million.

General and administrative expenses. General and administrative expenses were \$13.3 million and \$10.5 million for the three months ended June 30, 2023 and 2022, respectively. The change was primarily due to an increase in personnel costs of \$2.7 million and increases in travel and other expenditures of \$0.4 million.

Other income, net. Other income, net was \$2.0 million and \$0.7 million for the three months ended June 30, 2023 and 2022, respectively. The change was primarily due to income generated by our investment securities.

Comparison of the six months ended June 30, 2023 and 2022

The following table summarizes our results of operations for the six months ended June 30, 2023 and 2022 (*in thousands*):

	Six months ended June 30,		Dollar Change
	2023	2022	
Revenues	\$ 3,667	\$ 3,570	\$ 97
Operating expenses:			
Research and development	79,108	61,247	17,861
General and administrative	25,532	19,195	6,337
Total operating expenses	104,640	80,442	24,198
Loss from operations	(100,973)	(76,872)	(24,101)
Other income, net	3,999	880	3,119
Loss before equity method investment	(96,974)	(75,992)	(20,982)
Loss on equity method investment	—	(1,010)	1,010
Net loss	\$ (96,974)	\$ (77,002)	\$ (19,972)

Revenues. Revenues during the six months ended June 30, 2023 and 2022 primarily relate to licensing arrangements, including \$2.1 million from the Loyal License which was entered into during the first quarter of 2023. Revenues during the six months ended June 30, 2023 include \$1.2 million and \$0.4 million related to the Sanwa License and Sanwa Clinical Supply Agreement, respectively. 2022 revenues comprised of the upfront and over time revenues related to the Sanwa License.

Research and development expenses. Research and development expenses were \$79.1 million and \$61.2 million for the six months ended June 30, 2023 and 2022, respectively. The change was primarily due to an increase in personnel costs of \$13.9 million, increased consulting and outside services of \$2.9 million, and increased other expenditures of \$1.2 million.

The following table summarizes our primary external and internal research and development expenses for the six months ended June 30, 2023 and 2022 (*in thousands*):

	Six months ended June 30,		Dollar Change
	2023	2022	
External research and development expenses:			
Clinical trials	\$ 19,921	\$ 18,860	\$ 1,061
Contract manufacturing	5,763	9,638	(3,875)
Preclinical studies	8,353	6,168	2,185
Outside services	6,687	3,791	2,896
Other external research and development	22	35	(13)
Total external research and development expenses	40,746	38,492	2,254
Internal expenses:			
Payroll and benefits	24,322	13,829	10,493
Stock-based compensation	10,280	6,872	3,408
Facilities and related	1,733	1,286	447
Other internal research and development	2,027	768	1,259
Total internal research and development expenses	38,362	22,755	15,607
Total research and development expenses	\$ 79,108	\$ 61,247	\$ 17,861

The following table summarizes our research and development expenses by program for the six months ended June 30, 2023 and 2022 (*in thousands*):

	Six months ended June 30,		Dollar Change
	2023	2022	
Paltusotine	\$ 22,529	\$ 22,335	\$ 194
CRN04894	5,643	5,701	(58)
CRN04777	5,804	5,940	(136)
Discovery	5,137	2,827	2,310
Payroll and benefits	24,322	13,829	10,493
Stock-based compensation	10,280	6,872	3,408
Other	5,393	3,743	1,650
Total research and development expenses	\$ 79,108	\$ 61,247	\$ 17,861

Research and development expenses for our paltusotine program were \$22.5 million and \$22.3 million for the six months ended June 30, 2023 and 2022, respectively. The change was primarily due to an increase in consulting and outside services of \$1.0 million, an increase in travel and other expenditures of \$0.3 million, partially offset by decreased spending on manufacturing and development activities with our clinical and nonclinical activities of \$1.1 million.

Research and development expenses for our CRN04894 program were \$5.6 million and \$5.7 million for the six months ended June 30, 2023 and 2022, respectively. The change was primarily due to decreased spending on manufacturing and development activities with our clinical and nonclinical activities of \$0.4 million, partially offset by an increase in consulting and outside services of \$0.2 million, and an increase in travel and other expenditures of \$0.1 million.

Research and development expenses for our CRN04777 program were \$5.8 million and \$5.9 million for the six months ended June 30, 2023 and 2022, respectively. The change was primarily due to a decrease in consulting and outside services of \$0.3 million, partially offset by increased spending on manufacturing and development activities with our clinical and nonclinical activities of \$0.1 million.

Research and development expenses for our discovery programs were \$5.1 million and \$2.8 million for the six months ended June 30, 2023 and 2022, respectively. The change was primarily due to increased spending on manufacturing and development activities with our clinical and nonclinical activities of \$0.6 million and an increase in consulting and outside services of \$1.7 million.

Research and development expenses for payroll and benefits were \$24.3 million and \$13.9 million for the six months ended June 30, 2023 and 2022, respectively. The change was primarily due to an increase in headcount to support our ongoing programs.

Research and development expenses for stock-based compensation were \$10.3 million and \$6.9 million for the six months ended June 30, 2023 and 2022, respectively. The change was primarily due to an increase in headcount to support our ongoing programs.

Research and development expenses for our other programs were \$5.4 million and \$3.7 million for the six months ended June 30, 2023 and 2022, respectively. The change was primarily due an increase in travel and other expenditures of \$0.8 million, increased spending on manufacturing and development activities with our clinical and nonclinical activities of \$0.4 million, and an increase in facilities expenditures of \$0.4 million.

General and administrative expenses. General and administrative expenses were \$25.5 million and \$19.2 million for the six months ended June 30, 2023 and 2022, respectively. The change was primarily due to an increase in personnel costs of \$5.4 million and an increase in other expenditures of \$1.1 million.

Other income, net. Other income, net was \$4.0 million and \$0.9 million for the six months ended June 30, 2023 and 2022, respectively. The change was primarily due to income generated by our investment securities.

Loss on equity method investment. Loss on equity method investment was \$1.0 million for the six months ended June 30, 2022, as a result of our share of loss in Radionetics' net loss.

Cash Flows

We have incurred cumulative net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of June 30, 2023, we had unrestricted cash, cash equivalents and investment securities of \$264.5 million and an accumulated deficit of \$536.1 million.

The following table provides information regarding our cash flows for the six months ended June 30, 2023 and 2022 (*in thousands*):

	Six months ended June 30,	
	2023	2022
Net cash used in operating activities	\$ (86,453)	\$ (41,519)
Net cash provided by (used in) investing activities	80,191	(217,655)
Net cash provided by financing activities	13,142	120,772
Net change in cash, cash equivalents and restricted cash	<u>\$ 6,880</u>	<u>\$ (138,402)</u>

Operating Activities. Net cash used in operating activities was \$86.5 million and \$41.5 million for the six months ended June 30, 2023 and 2022, respectively. The increase in cash used in operations was primarily attributable to higher personnel costs. The net cash used in operating activities during the six months ended June 30, 2023, was primarily due to our net loss of \$97.0 million and a \$5.1 million change in operating assets and liabilities adjusted for \$15.6 million of noncash charges, primarily for stock-based compensation. Net cash used in operating activities during the six months ended June 30, 2022 was primarily due to our net loss of \$77.0 million adjusted for \$15.0 million of noncash charges, primarily for stock-based compensation and loss on the investment of Radionetics, and a \$20.5 million change in operating assets and liabilities.

Investing activities. Investing activities consist primarily of purchases and maturities of investment securities and, to a lesser extent, the cash outflow associated with purchases of property and equipment. Such activities resulted in a net inflow of funds of approximately \$80.2 million during the six months ended June 30, 2023, compared to a net outflow of funds of approximately \$217.7 million during the six months ended June 30, 2022.

Financing activities. Net cash provided by financing activities was \$13.1 million and \$120.8 million for the six months ended June 30, 2023 and 2022, respectively. The net cash provided by financing activities during 2023 and 2022 resulted from proceeds received from the sale of common stock and cash received from the exercise of stock options.

Liquidity and Capital Resources

We believe that our existing capital resources, together with investment income, will be sufficient to satisfy our current and projected funding requirements for at least the next twelve months. However, our forecast of the period through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

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

- the type, number, scope, progress, expansions, results, costs and timing of our preclinical studies and clinical trials of our product candidates which we are pursuing or may choose to pursue in the future;
- the costs and timing of manufacturing for our product candidates, including commercial manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase.
- the timing and the extent of any Australian Tax Incentive refund and future grant revenues that we receive;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidate is approved;
- our ability to achieve sufficient market acceptance, adequate coverage and reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- costs associated with any products or technologies that we may in-license or acquire;
- the funding of any co-development arrangements we enter into; and
- our ability to participate in future equity offerings by Radionetics.

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

In August 2019, we entered into a Sales Agreement, or the Sales Agreement, with SVB Leerink LLC and Cantor Fitzgerald & Co., or collectively, the Sales Agents, under which we may, from time to time, sell shares of our common stock through the Sales Agents, or the ATM Offering. Sales of our common stock made pursuant to the Sales Agreement will be made directly on or through the Nasdaq Global Select Market under our effective shelf Registration Statement on Form S-3 filed on August 10, 2021, or the 2021 Shelf Registration Statement, and a prospectus supplement filed on August 12, 2022 relating to the offer and sale of up to \$150.0 million of shares of our common stock in the ATM Offering by means of ordinary brokers' transactions at market prices. Additionally, under the terms of the Sales Agreement, we may also sell shares of our common stock through the Sales Agents, on the Nasdaq Global Select Market or otherwise, at negotiated prices or at prices related to the prevailing market price. We are not obligated to, and we cannot provide any assurances that we will continue to, make any sales of the shares under the Sales Agreement. The Sales Agreement may be terminated by either Sales Agent (with respect to itself) or us at any time upon 10 days' notice to the other parties, or by either Sales Agent, with respect to itself, at any time in certain circumstances, including the occurrence of a material adverse change. We will pay the Sales Agents a commission for their services in acting as agent in the sale of common stock in an amount equal to 3% of the gross sales price per share sold. During 2020, we issued 275,764 shares of common stock in the ATM Offering for net proceeds of \$6.4 million, after deducting commissions, pursuant to our Shelf Registration Statement on Form S-3, which became effective on August 29, 2019, or the 2019 Shelf Registration Statement. The 2019 Shelf Registration Statement included a prospectus covering the

offering, issuance, and sale of up to \$75.0 million of our common stock from time to time through the ATM Offering. The 2019 Shelf Registration Statement expired on August 29, 2022. No shares were issued under the ATM Offering during the three and six months ended June 30, 2023 and 2022 pursuant to the 2019 Shelf Registration Statement.

On April 18, 2022, we completed an underwritten follow-on offering of 5,625,563 shares of our common stock at a price to the public of \$22.22 per share. Net proceeds from the offering were approximately \$117.2 million, after underwriting discounts and commissions and offering costs of approximately \$7.8 million.

As discussed above, on August 12, 2022, we filed with the SEC a prospectus supplement to the 2021 Shelf Registration Statement pursuant to Rule 424(b) under the Securities Act of 1933, as amended, relating to the offer and sale of up to \$150 million of shares of our common stock from time to time to or through the Sales Agents pursuant to the Sales Agreement. During the three and six months ended June 30, 2023, we issued 522,807 shares of common stock in the ATM Offering for net proceeds of approximately \$11.3 million, after deducting commissions, pursuant to the 2021 Shelf Registration Statement.

2022 Lease

On September 9, 2022, we entered into a lease agreement for laboratory and office space in San Diego, California, or the 2022 Lease. We expect to move our corporate headquarters to this new facility upon our substantial completion of improvements and written landlord consent, which is expected to occur in the second half of 2023.

Under the terms of the 2022 Lease, our expected future monthly minimum lease payments of \$0.5 million, with six months of rent abatement in the first year, start on the earlier of (i) the date which is ten (10) months after substantial completion of demolition work, or (ii) the date of the substantial completion of improvements and first occupancy for business purposes, and the term expires on the date immediately preceding the one hundred thirty-seventh (137th) monthly anniversary of this lease payment start date. Lease payments are subject to annual 3% increases. We are also responsible for certain operating expenses and taxes during the term of the 2022 Lease. The 2022 Lease provides us with specified tenant improvement and landlord work allowances. We have (i) two options to extend the term of the 2022 Lease for an additional period of five (5) years each, and (ii) a right of first offer on adjacent space to the new facility, subject to the terms and conditions of the 2022 Lease.

The 2022 Lease did not commence as of June 30, 2023, since the Company did not control the facility. The lease will be measured and recognized upon lease commencement.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our cash, cash equivalents and investment securities consist of cash held in readily available checking and money market accounts as well as short-term debt securities. We are exposed to market risk related to fluctuations in interest rates and market prices. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition or results of operations.

Foreign Currency

We contract with vendors, CROs and investigational sites in several foreign countries, including countries in South America, Europe and the Asia Pacific. As such, we have exposure to fluctuations in foreign currency rates in connection with these agreements. We do not hedge our foreign currency exchange rate risk. We believe this exposure to be immaterial and, to date, we have not incurred any material adverse effects from foreign currency changes on these contracts.

In January 2017, we formed CAPL, a wholly-owned subsidiary in Australia, which exposes us to foreign currency exchange rate risk. The functional currency of CAPL is the United States dollar. Assets and liabilities of our foreign subsidiary that are not denominated in the functional currency are remeasured into U.S. dollars at foreign currency exchange rates in effect at the balance sheet date except for nonmonetary assets and capital accounts, which are remeasured at historical foreign currency exchange rates in effect at the date of transaction. Expenses are generally remeasured at foreign currency exchange rates which approximate average rates in effect during each period. Net realized and unrealized gains and losses from foreign currency transactions and remeasurement are reported in other income (expense), net, in the condensed consolidated statements of operations and totaled (\$6,000) and (\$61,000) for the three and six months ended June 30, 2023, respectively, and (\$80,000) and (\$63,000) for the three and six months ended June 30, 2022, respectively.

As of June 30, 2023 and 2022, the impact of a theoretical 10% change in the exchange rate of the Australian dollar would not result in a material gain or loss. To date, we have not hedged exposures denominated in foreign currencies.

Inflation Risk

Inflationary factors, such as increases in the cost of our materials, supplies, and overhead costs may adversely affect our operating results. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some adverse effect if inflation rates rise. Significant adverse changes in inflation and prices in the future could result in material losses.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports 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 chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is 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, 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 SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial 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 chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective as of June 30, 2023 at the reasonable assurance level.

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Risk Factors

We do not believe that there have been any material changes to the risk factors set forth in Part II, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022 and Part II, Item 1A of our Quarterly Report for the quarter ended March 31, 2023.

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

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Rule 10b5-1 Trading Plans

During the three months ended June 30, 2023, none of our officers (as defined in Rule 16a-1(f)) or directors adopted or terminated any Rule 10b5-1 trading arrangement or any non-Rule 10b5-1 trading arrangement, as each such term is defined in Item 408 of Regulation S-K.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation	8-K	001-38583	3.1	7/20/2018	
3.2	Amended and Restated Bylaws	8-K	001-38583	3.1	4/14/2020	
4.1	Specimen Stock Certificate Evidencing the Shares of Common Stock	S-1/A	333-225824	4.1	7/9/2018	
10.1#	Non-Employee Director Compensation Program, as amended effective as of April 24, 2023	10-Q	001-38583	10.2	5/9/2023	
31.1	Certification of Chief Executive Officer pursuant to Rule 13(a)-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2002					X
31.2	Certification of Chief Financial Officer pursuant to Rule 13(a)-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2002					X
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant 18. U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002					X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)					X

Indicates management contract or compensatory plan.

* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Crinetics Pharmaceuticals, 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 this Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Crinetics Pharmaceuticals, Inc.

Date: August 8, 2023

By: /s/ R. Scott Struthers, Ph.D.
R. Scott Struthers, Ph.D.
President and Chief Executive Officer
(Principal executive officer)

Date: August 8, 2023

By: /s/ Marc J.S. Wilson
Marc J.S. Wilson
Chief Financial Officer
(Principal financial and accounting officer)

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

I, R. Scott Struthers, Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Crinetics Pharmaceuticals, 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 controls over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2023

/s/ R. Scott Struthers, Ph.D.

R. Scott Struthers, Ph.D.

President and Chief Executive Officer

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

I, Marc J.S. Wilson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Crinetics Pharmaceuticals, 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 controls over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2023

/s/ Marc J.S. Wilson

Marc J.S. Wilson
Chief Financial Officer

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Crinetics Pharmaceuticals, Inc. (the “Company”) hereby certifies, to his knowledge, that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended June 30, 2023 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

/s/ R. Scott Struthers, Ph.D.

R. Scott Struthers, Ph.D.

President and Chief Executive Officer

Date: August 8, 2023

CERTIFICATION OF CHIEF FINANCIAL OFFICER

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Crinetics Pharmaceuticals, Inc. (the “Company”) hereby certifies, to his knowledge, that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended June 30, 2023 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

/s/ Marc J.S. Wilson

Marc J.S. Wilson

Chief Financial Officer

Date: August 8, 2023
