## 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, 2022

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)

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

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

	Trading	
Title of each class	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  $\square$  No  $\square$ 

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," "scelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	
Non-accelerated filer	Smaller reporting company	$\checkmark$
	Emerging growth company	$\checkmark$

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 9, 2022, the registrant had 53,752,778 shares of common stock (\$0.001 per share par value) outstanding.

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

26-3744114

92121 (Zip code)

### **CRINETICS PHARMACEUTICALS, INC.**

## QUARTERLY REPORT ON FORM 10-Q For the Quarter Ended June 30, 2022

## TABLE OF CONTENTS

## PART I – FINANCIAL INFORMATION

Page

Item 1.	Condensed Consolidated Financial Statements (unaudited):	3
	Condensed Consolidated Balance Sheets as of June 30, 2022 and December 31, 2021	3
	Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2022 and 2021	4
	Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2022 and 2021	5
	Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2022 and 2021	6
	Notes to Condensed Consolidated Financial Statements	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	21
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	31
Item 4.	Controls and Procedures	31
	PART II — OTHER INFORMATION	
Item 1.	Legal Proceedings	32
Item 1A.	Risk Factors	32
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	32
Item 3.	Defaults Upon Senior Securities	32
Item 4.	Mine Safety Disclosures	32
Item 5.	Other Information	32
Item 6.	Exhibits	33

## PART I — FINANCIAL INFORMATION

## **Crinetics Pharmaceuticals, Inc.**

### **Condensed Consolidated Balance Sheets**

(In thousands)

		June 30, 2022	I	December 31, 2021
Assets		(Unaudited)		
Current assets:				
Cash and cash equivalents	\$	62,293	\$	200,695
Investment securities	·	346,213	•	133,012
Prepaid expenses and other current assets		7,779		11,013
Total current assets		416,285		344,720
Property and equipment, net		3,152		2,825
Operating lease right-of-use asset		1,697		1,892
Derivative asset		99		68
Investment in Radionetics				1,010
Restricted cash		500		500
Total assets	\$	421,733	\$	351,015
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable and accrued expenses	\$	17,132	\$	8,468
Accrued compensation and related expenses	-	5,447	*	6,588
Deferred revenue		2,543		
Other current liabilities		993		939
Total current liabilities		26,115		15,995
Operating lease liability, non-current		2,565		3,074
Deferred revenue, non-current		6,888		_
Unvested stock liability				2
Total liabilities		35,568		19,071
Commitments and contingencies (Note 7)				
Stockholders' equity:				
Preferred stock, \$0.001 par; 10,000 shares authorized; no shares issued or outstanding at June 30, 2022 or at December 31, 2021		_		_
Common stock and paid-in capital, \$0.001 par; 200,000 shares authorized; 53,720 shares issued and outstanding at June 30, 2022;				
47,598 shares issued and 47,597 shares outstanding at December 31, 2021		742,041		607,581
Accumulated other comprehensive income		(3,619)		(382)
Accumulated deficit		(352,257)		(275,255)
Total stockholders' equity		386,165		331,944
Total liabilities and stockholders' equity	\$	421,733	\$	351,015

See the accompanying notes to these unaudited condensed consolidated financial statements. 3

#### **Crinetics Pharmaceuticals, Inc.**

## Condensed Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except per share data) (Unaudited)

	Three months o	ended	June 30,	Six months en	June 30,	
	2022		2021	2022		2021
License revenues	\$ 439	\$		\$ 3,570	\$	—
Operating expenses:						
Research and development	32,995		20,487	61,247		38,071
General and administrative	10,489		5,602	19,195		10,936
Total operating expenses	43,484		26,089	 80,442		49,007
Loss from operations	(43,045)		(26,089)	 (76,872)		(49,007)
Other income (expense):						
Interest income	720		23	913		53
Other expense, net	(81)		(29)	(64)		(42)
Change in valuation of derivative asset	 31			 31		
Total other expense, net	 670		(6)	 880		11
Loss before equity method investment	 (42,375)		(26,095)	(75,992)		(48,996)
Loss on equity method investment	—			(1,010)		
Net loss	\$ (42,375)	\$	(26,095)	\$ (77,002)	\$	(48,996)
Net loss per share:						
Net loss per share - basic and diluted	\$ (0.81)	\$	(0.70)	\$ (1.54)	\$	(1.40)
Weighted average shares - basic and diluted	52,522		37,061	 50,130		35,048
Other comprehensive income (loss):	 			 		
Unrealized loss on investment securities	\$ (1,427)	\$	(9)	\$ (3,237)	\$	(15)
Comprehensive loss	\$ (43,802)	\$	(26,104)	\$ (80,239)	\$	(49,011)

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

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

## (In thousands) (Unaudited)

		(0	nauuneu)			
	Common Stock Shares		Common stock and Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
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 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	53,720	\$	742,041	\$ (3,619)	\$ (352,257)	\$ 386,165
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 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	53,720	\$	742,041	\$ (3,619)	\$ (352,257)	\$ 386,165
Balance at April 1, 2021	33,017	\$	339,976	\$ 19	\$ (190,515)	\$ 149,480
Issuance of common stock, net of \$2.4 million of transaction costs	4,562		72,558	_	_	72,558
Stock issued under Stock Purchase Plan	47		522	_	_	522
Vesting of shares subject to repurchase	5		6	_	_	6
Exercise of stock options	49		745	—	—	745
Stock-based compensation	—		4,233	—	—	4,233
Comprehensive loss	_		—	(9)	_	(9)
Net loss				 	 (26,095)	 (26,095)
Balance at June 30, 2021	37,680	\$	418,040	\$ 10	\$ (216,610)	\$ 201,440
Balance at January 1, 2021	33,001	\$	336,508	\$ 25	\$ (167,614)	\$ 168,919
Issuance of common stock, net of \$2.4 million of transaction costs	4,562		72,558	_	_	72,558
Stock issued under Stock Purchase Plan	47		522	_	_	522
Vesting of shares subject to repurchase	8		11	—	—	11
Exercise of stock options	62		802	_	_	802
Stock-based compensation	—		7,639	_	_	7,639
Comprehensive loss	—		—	(15)	—	(15)
Net loss				 _	 (48,996)	 (48,996)
Balance at June 30, 2021	37,680	\$	418,040	\$ 10	\$ (216,610)	\$ 201,440

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

## **Crinetics Pharmaceuticals, Inc.**

## **Condensed Consolidated Statements of Cash Flows**

(In thousands) (Unaudited)

			ths endered as the second s	d
		2022		2021
Operating activities:				
Net loss	\$	(77,002)	\$	(48,996)
Reconciliation of net loss to net cash used in operating activities:				
Stock-based compensation		12,886		7,639
Depreciation and amortization		455		454
Noncash lease expense		195		163
Accretion of purchase discounts and amortization		<b>517</b>		170
of premiums on investment securities, net		517		170
Loss on equity method investment		1,010		
Change in valuation of derivative asset		(31)		
Other, net		_		(1)
Increase (decrease) in cash resulting from changes in:		2 2 2 4		(2.11)
Prepaid expenses and other assets		3,234		(941)
Accounts payable and accrued expenses		8,241		1,901
Deferred revenue		9,431		
Operating lease liability		(455)		(405)
Net cash used in operating activities		(41,519)		(40,016)
Investing activities:				
Purchases of investment securities		(247,572)		(2,535)
Maturities of investment securities		30,617		55,153
Purchases of property and equipment		(700)		(278)
Net cash (used in) provided by investing activities		(217,655)		52,340
Financing activities:				
Proceeds from issuance of common stock, net of \$7.8 million (2022) and \$2.4 million (2021) of transaction costs		117,255		72,558
Proceeds from exercise of stock options		3,517		802
Net cash provided by financing activities		120,772		73,360
Net change in cash, cash equivalents and restricted cash		(138,402)		85,684
Cash, cash equivalents and restricted cash at beginning of period		201,195		93,587
Cash, cash equivalents and restricted cash at end of period	\$	62,793	\$	179,271
	φ	02,775	Φ	179,271
Components of cash, cash equivalents and restricted cash:	¢	(2.202	¢	170 771
Cash and cash equivalents Restricted cash	\$	62,293	\$	178,771
	¢	500	¢	500
Cash, cash equivalents and restricted cash at end of period	\$	62,793	\$	179,271
Noncash investing and financing activities:				
Change in unvested stock liability	\$	2	\$	11
Stock issued under Stock Purchase Plan	\$	813	\$	522
Amounts accrued for follow-on offering costs	\$	13	\$	
Amounts accrued for purchases of property and equipment	\$	82	\$	
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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, 2022, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2022 and 2021, the condensed consolidated statements of stockholders' equity for the three and six months ended June 30, 2022 and 2021, and the condensed consolidated statements of cash flows for the six months ended June 30, 2022 and 2021, 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, 2022 and the results of its operations and cash flows for the six months ended June 30, 2022 and 2021 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, 2022 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 \$352.3 million as of June 30, 2022.

As of June 30, 2022, the Company had \$408.5 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 future prospects. There can be no assurance as to the availability or terms upon which such financing and capital might be available in the future.

COVID-19



The COVID-19 pandemic has caused significant business disruption around the globe. The extent of the impact of COVID-19 on the Company's operational and financial performance will depend on certain developments, including the duration of the pandemic and the impact on the Company's clinical trials, employees and vendors. To the extent possible, and consistent with applicable guidance from federal, state and local authorities, the Company is conducting business as usual, with necessary or advisable modifications to employee travel. The Company will continue to actively monitor the evolving situation related to COVID-19 and may take further actions that alter its operations, including those that may be required by federal, state or local authorities, or that the Company determines are in the best interests of its employees and other third parties with whom the Company does business. While the pandemic has not yet had a material effect on the Company's financial results, the degree to which COVID-19, including the impact of new variants of the virus that causes COVID-19, may impact the Company's future financial condition or results of operations is uncertain. A prolonged outbreak could have a material adverse impact on financial results and business operations of the Company, including the timing and ability of Company to complete certain clinical trials and other efforts required to advance the development of its drug candidates and raise additional capital.

## 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 equity method investment. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

#### **Equity Method Investment**

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.

As discussed in Note 8, in October 2021, the Company, together with 5AM Ventures ("5AM") and Frazier Healthcare Partners ("Frazier"), announced the formation of Radionetics Oncology, Inc. ("Radionetics"). Radionetics aims to develop a deep pipeline of novel, targeted, nonpeptide radiopharmaceuticals for the treatment of a broad range of oncology indications. 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. The Company records its share of Radionetics income (loss) outside of operations in the statements of operations and comprehensive loss on a quarterly lag. Since the Company's investment in Radionetics was obtained on October 15, 2021, the Company recorded its share of income (loss) beginning in the first quarter of 2022. The Company's equity method investment in Radionetics was written down to zero during the first quarter of 2022 as a result of the allocation of the Company's share of losses of the investee.

#### **Fair Value Measurements**

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

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

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

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

The carrying amounts of the Company's 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 lease 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 included in earnings and are derived using the specific identification method for determining the cost of securities sold. The Company has not realized any significant gains or losses on sales of available-for-sale investment securities during any of the periods presented. As all the Company's investment holdings are in the form of debt securities, unrealized gains and losses that are determined to be temporary in nature are reported as a component of accumulated other comprehensive income (loss). A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the establishment of a new cost basis for the security. Interest income is recognized when earned and is included in investment income, as are the amortization of purchase premiums and accretion of purchase discounts on investment securities.

#### **Derivative Asset**

Derivatives are recorded at fair value and changes in fair value are recorded through the statements of operations and comprehensive loss each period. The Company has a single derivative instrument, a warrant ("Radionetics Warrant") received on October 15, 2021, 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 Company records the Radionetics Warrant as long-term on the balance sheets due to the lack of marketability, such that it is not expected to be available for current operations. Changes in fair value of the Radionetics Warrant are recognized in other income (expense) 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 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 minimum lease payments is recognized on a straight-line basis over the lease term.

#### **Revenue Recognition**

The Company has generated revenue from licensing 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, 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 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 develops assumptions under the adjusted market based approach that require judgment to determine the standalone selling price for license-related performance obligations, which may include 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, 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. Revenue is recorded proportionally as costs are incurred. 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 over time 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.

Costs incurred under contracts with contract research organizations that conduct and manage the Company's clinical trials are also included in research and development 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, as a result 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 Australian Tax Incentive will be received, the relevant expenditure has been incurred, and the amount can be reliably measured.

The Company recognized a reduction to R&D expense of \$0.2 million and \$0.3 million for the three and six months ended June 30, 2022, respectively. For each of the three and six months ended June 30, 2021, the Company recognized a reduction to R&D expense of \$0.2 million.

#### **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 gain or loss on the Company's investment securities held for all periods presented.

#### **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 would be antidilutive.

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

	As of Ju	ne 30
	2022	2021
Common stock awards	8,801	6,145
Unvested common stock subject to repurchase	—	9
Total	8,801	6,154

#### **Recently Adopted Accounting Pronouncements**

ASU 2021-04

In May 2021, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2021-04, *Earnings Per Share* ("Topic 260"), *Debt-Modifications and Extinguishments* ("Subtopic 470-50"), *Compensation-Stock Compensation* ("Topic 718"), and *Derivatives and Hedging-Contracts in Entity's Own Equity* ("Subtopic 815-40"): *Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*, which intends to clarify and reduce diversity in



an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The Company adopted ASU 2021-04 as of January 1, 2022, which did not have an impact on its condensed consolidated financial statements.

#### **Recent Accounting Pronouncements**

## ASU 2016-13

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments" ("Topic 326"), subsequently amended by various standard updates. 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 similar to current GAAP, however Topic 326 will require that credit losses be presented as an allowance rather than as a write-down. The amendments in this new standard indicate that an entity should not use the length of time a security has been in an unrealized loss position to avoid recording a credit loss. In addition, in determining whether a credit loss exists, the amendments in this new accounting standard also remove the requirements to consider the historical and implied volatility of the fair value of a security and recoveries or declines in fair value after the balance sheet date. This ASU update affects entities holding financial assets and net investment in leases that are not accounted for at fair value of adoption. This update is effective for the Company for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company has begun the analysis of this new standard for its available for sale debt securities regarding presentation and qualitative factors of credit losses. The Company continues to evaluate the impact of the pending adoption of this new standard on its condensed consolidated financial statements. The impact of the adop

#### **3. INVESTMENT SECURITIES**

The Company reports its available-for-sale investment securities at their estimated fair values based on quoted market prices for identical or similar instruments. The following is a summary of the available-for-sale investment securities held by the Company as of June 30, 2022 and December 31, 2021 (*in thousands*):

			As of June	e 30, 2	2022	
	A	Amortized Cost	Gross Unrealized Gains		Gross Unrealized Losses	Fair Market Value
Available-for-sale investment securities:						
U.S. government and agency obligations	\$	185,330	\$ 9	\$	(1,538)	\$ 183,801
Certificates of deposit		6,219			(75)	6,144
Corporate debt securities		151,887	2		(2,013)	149,876
Commercial paper		3,992				3,992
Asset-backed securities		2,404	—		(4)	2,400
Total	\$	349,832	\$ 11	\$	(3,630)	\$ 346,213

				As of Decem	ber 3	1, 2021	
	А	mortized Cost	_	Gross Unrealized Gains		Gross Unrealized Losses	Fair Market Value
Available-for-sale investment securities:							
U.S. government and agency obligations	\$	54,637	\$		\$	(180)	\$ 54,457
Certificates of deposit		5,735		1		(4)	5,732
Corporate debt securities		70,600		6		(204)	70,402
Asset-backed securities		2,421				—	2,421
Total	\$	133,393	\$	7	\$	(388)	\$ 133,012

As of June 30, 2022 and December 31, 2021, available-for-sale investment securities by contractual maturity were as follows (in thousands):

	 As of Jun	e 30, 20	)22	 As of Decen	nber 31,	2021
	Amortized Cost		Fair Market Value	 Amortized Cost		Fair Market Value
Available-for-sale investment securities:						
Due in one year or less	\$ 235,421	\$	233,722	\$ 31,101	\$	31,078
Due after one year through five years	114,411		112,491	102,292		101,934
Total	\$ 349,832	\$	346,213	\$ 133,393	\$	133,012

The Company reviewed its investment holdings as of June 30, 2022 and December 31, 2021 and determined that its unrealized losses were not considered to be other-than-temporary based upon (i) the financial strength of the issuing institution and (ii) the fact that no securities have been in an unrealized loss position for twelve months or more. As such, the Company has not recognized any impairment in its financial statements related to its available-for-sale investment securities.

#### 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 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 all the Company to maintain an aggregate equity interest of 22% of the fully diluted capitalization of Radionetics. The valuation method and primary inputs used in valuing the Radionetics Warrant are discussed in Note 8. Such valuation is based on valuations provided by a third-party valuation specialist using unobservable inputs due to little to no market data (Level 3 inputs). During the three and six months ended June 30, 2022, the Company recorded \$31,000 of income in the accompanying condensed consolidated statements of operations and comprehensive loss related to the change in value of the Radionetics Warrant, which was reassessed as of June 30, 2022.

Financial assets measured at fair value on a recurring basis as of June 30, 2022 and December 31, 2021 were as follows (in thousands):

		As of Jun	e 30, 2	2022	
	 Level 1	Level 2		Level 3	Total
Investment securities:					
U.S. government and agency obligations	\$ 149,890	\$ 33,911	\$		\$ 183,801
Certificates of deposit		6,144			6,144
Corporate debt securities	_	149,876			149,876
Commercial paper	_	3,992			3,992
Asset-backed securities		2,400			2,400
Total Investment securities	149,890	196,323			346,213
Derivative Assets:					
Radionetics Warrant				99	99
Total assets measured at fair value	\$ 149,890	\$ 196,323	\$	99	\$ 346,312



	As of December 31, 2021							
		Level 1		Level 2		Level 3		Total
Investment securities:								
U.S. government and agency obligations	\$	44,984	\$	9,473	\$	—	\$	54,457
Certificates of deposit				5,732		—		5,732
Corporate debt securities				70,402		—		70,402
Asset-backed securities				2,421				2,421
Total Investment securities		44,984		88,028		—		133,012
Derivative Assets:								
Radionetics Warrant				—		68		68
Total assets measured at fair value	\$	44,984	\$	88,028	\$	68	\$	133,080

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, 2022 or year ended December 31, 2021.

## **5. BALANCE SHEET DETAILS**

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

	June 30, 2022			December 31, 2021
Prepaid research and development costs	\$	3,755	\$	7,184
Australian tax incentive receivable		577		977
Prepaid insurance		287		888
Interest receivable		1,155		499
Due from Radionetics (Note 8)		379		553
Other		1,626		912
Total	\$	7,779	\$	11,013

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

	June 30, 2022			December 31, 2021
Leasehold improvements	\$	3,516	\$	3,516
Lab equipment		2,671		1,889
Office equipment		859		859
Computers and software		41		41
Property and equipment at cost		7,087		6,305
Less accumulated depreciation and amortization		3,935		3,480
Total	\$	3,152	\$	2,825

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

	June 30, 2022		December 31, 2021
Accounts payable	\$ 9,03	9 \$	3,422
Other accrued expenses	1,77	3	860
Accrued research and development costs	6,32	)	4,186
Total	\$ 17,13	2 \$	8,468

#### 6. OPERATING LEASE

In February 2018, as amended in March 2018, the Company entered into a non-cancelable operating lease for a new facility in San Diego, California. The 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 lease for an additional five years and has a termination option subject to early termination fees. The 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 facility lease does not have a stated rate and the implicit rate was not readily determinable.

Under the terms of the lease, the Company provided the lessor with an irrevocable letter of credit in the amount of \$0.5 million. The lessor is entitled to draw on the letter of credit in the event of any default by the Company under the terms of the lease.

As of June 30, 2022, future minimum payments under non-cancellable operating leases were as follows (in thousands):

Year ending December 31,	imum ments
2022 (6 months)	\$ 610
2023	1,244
2024	1,280
2025	871
Total future minimum lease payments	4,005
Less imputed interest	(447)
Total operating lease liability	3,558
Less operating lease liability, current	(993)
Operating lease liability, non-current	\$ 2,565

Lease cost is recorded on a straight-line basis over the term of the Company's facility lease. Rent expense was \$0.3 million and \$0.6 million for the three and six months ended June 30, 2022, respectively, and \$0.3 million and \$0.6 million for the three and six months ended June 30, 2021, respectively. As of June 30, 2022 and December 31, 2021, the Company's operating lease weighted average remaining term was 3.1 and 3.6 years, respectively. As of June 30, 2022 and December 31, 2021, 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 each of the three and six months ended June 30, 2022 and June 30, 2021, 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. LICENSE AGREEMENTS

#### **Radionetics Oncology, Inc.**

#### Formation

In October 2021, the Company, together with 5AM and Frazier, announced the formation of Radionetics. Radionetics aims to develop a deep pipeline of novel, targeted, nonpeptide radiopharmaceuticals for the treatment of a broad range of oncology indications.

#### Collaboration and License Agreement

The Company and Radionetics entered into the collaboration and license agreement ("CLA"), under which the Company granted to Radionetics an exclusive world-wide license to its radiotherapeutics technology platform and associated intellectual property for use in developing radiotherapeutics and related radio-imaging agents, including exclusive rights to the underlying intellectual property on certain preclinical drug candidates. Under the CLA, the Company will not be supporting or maintaining the intellectual property and does not plan on continuing to undertake those activities from which the utility of the intellectual property is derived. The collaborative provisions per the CLA are deemed to be protective measures for the advancement of the technology and not deemed to be a separate performance obligation. The Company assessed the CLA and concluded that Radionetics is a customer within the CLA. The performance obligation under the CLA consisted of the license and know-how of the technology that was transferred at the inception of the CLA.

In exchange, the Company received 50,500,000 shares of common stock of Radionetics, which represents an initial majority stake in Radionetics of 64%, and 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 exercise price of the Radionetics Warrant is \$0.00001 and it is exercisable at any time and has a term of 10 years. As of June 30, 2022, the Company had a 56% majority ownership stake in Radionetics.

These upfront noncash considerations were valued at \$1.1 million, which were comprised of \$1.0 million for the Company's share of Radionetics common stock and \$0.1 million for the Radionetics Warrant. The CLA is for functional intellectual property which was transferred at the inception of the CLA. The Company does not have an ongoing performance obligation to support or maintain the licensed intellectual property under the CLA. In October 2021, the entire amount of the upfront noncash consideration of \$1.1 million was recognized as license revenue upon the Company's transfer of the license under the CLA.



In addition to the upfront non-cash considerations, the Company may receive potential sales milestones in excess of \$1.0 billion and single-digit royalties on net sales. As there have been no sales to date, no sales-based milestones or royalties were recognized to date.

#### Investment in Radionetics

The Company applied the VIE model to its variable interests in Radionetics and concluded Radionetics is a VIE due to its insufficient equity to finance its activities without additional subordinated financial support.

The Company then evaluated whether it is the primary beneficiary of Radionetics by identifying Radionetics' key activities: (1) research and development activities, (2) financing decisions, and (3) determining the strategic direction of Radionetics. Power over research and development activities are made by unanimous vote by members of the research and development committee, in which no party has power. Power for financing decisions and setting strategic direction rests with the Radionetics' board of directors, and no party was determined to be in control since the Radionetics board of directors is comprised of 4 members for which Crinetics, 5AM and Frazier are entitled to appoint (and replace, as needed) their board designee while the fourth independent member must be mutually agreed to by all three investors. Radionetics' management is entirely separate from the Company and is determined by Radionetics' board of directors. As the Company does not control any of Radionetics' key activities, it is not the primary beneficiary of the VIE and does not consolidate Radionetics.

The Company accounted for its investment in Radionetics under the equity method of accounting due to its ability to exercise significant influence through its board seat and involvement in R&D activities, among other factors. The Company's initial investment in Radionetics was recorded at the fair value of common stock received in the amount of \$1.0 million.

The Company's maximum exposure to loss of Radionetics is limited to carrying value of its equity method investment in Radionetics and the Radionetics Warrant. The Company has no obligation to fund the operations of Radionetics and has not provided significant explicit or implicit support to Radionetics that was not contractually required. The financial statements of Radionetics are not received sufficiently timely for the Company to record its portion of earnings or loss in the current condensed consolidated financial statements and therefore the Company reports its portion of earnings or loss on a one quarter lag. The Company accounted for its share in Radionetics' loss as of December 31, 2021 during the first quarter of 2022. The Company's investment in Radionetics was written down to zero during the first quarter of 2022 as a result of the allocation of the Company's share of losses of the investee.

#### Other Radionetics Transactions

During the year ended December 31, 2021, Radionetics completed a \$30.0 million convertible notes financing with 5AM and Frazier as the sole participants.

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, 2022 and December 31, 2021, the Company had approximately \$0.4 million and \$0.6 million, respectively, 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 has evaluated these reimbursements and concluded that these reimbursements are not performance obligations for which the Company is acting as the principal and therefore these amounts have been included within operating expenses in the accompanying statements of operations and comprehensive loss in the period incurred.

#### 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 considered to be 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 as the Sanwa License is for functional intellectual property 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.

During the three and six months ended June 30, 2022, \$0.4 million and \$3.6 million, respectively, of the \$13 million upfront payment was recognized as license revenues in the accompanying condensed consolidated statements of operations and comprehensive loss, and as of June 30, 2022, \$2.5 million and \$6.9 million is included as current deferred revenues and non-current deferred revenues, respectively, in the accompanying condensed consolidated balance sheets. Deferred revenues are expected to be recognized over the duration of certain paltusotine studies conducted by the Company. 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 as of June 30, 2022.

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. No supply purchases were made by Sanwa through the Sanwa Clinical Supply Agreement during the six months ended June 30, 2022.

## 9. STOCKHOLDERS' EQUITY

#### **Stock Offerings**

On April 12, 2021, the Company completed an underwritten follow-on offering of 4,562,044 shares of its common stock at a price to the public of \$16.44 per share. Proceeds from the offering were approximately \$72.6 million, net of underwriting discounts and commissions and offering costs of \$2.4 million. The shares were registered pursuant to the Company's Shelf Registration Statement discussed below.

On July 28, 2021, the Company entered into a stock purchase agreement for the private placement of 851,306 shares of its common stock at a price of \$17.62 per share (the "Private Placement"), which shares were issued on July 30, 2021. Proceeds from the offering were approximately \$15.0 million.

On October 21, 2021, the Company completed an underwritten follow-on offering of 8,712,400 shares of its common stock at a price to the public of \$19.80 per share. Proceeds from the offering were approximately \$162.0 million, net of underwriting discounts and commissions and offering costs of \$10.5 million. The shares were registered pursuant to the Company's 2021 Shelf Registration Statement discussed below.

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 Statement and ATM Offerings

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

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 having an aggregate offering price of up to \$75.0 million through the Sales Agents (the "ATM Offering"). The 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. The shares to be sold under the Sales Agreement may be issued and sold pursuant to the Shelf Registration Statement.

To date, the Company has issued 275,764 shares of common stock in the ATM Offering for net proceeds of \$6.4 million, after deducting commissions. The Company has not issued any additional shares of common stock in the ATM Offering since the first quarter of 2020.

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.

#### **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. As of June 30, 2022, 207,900 shares were available for future issuance under the 2021 Inducement Plan.

#### 2018 Incentive Award Plan

In July 2018, the Company adopted the 2018 Incentive Award Plan (the "2018 Plan"). 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, 2022, 2,116,691 shares 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, 2022, an additional 2,379,911 shares became available for future issuance under the 2018 Plan.

#### 2015 Stock Incentive Plan

In February 2015, the Company adopted the Crinetics Pharmaceuticals, Inc. 2015 Stock Incentive Plan (the "2015 Plan"), 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.

Certain awards under the 2015 Plan allowed for exercise prior to vesting. Shares issued under such early-exercise provisions are subject to repurchase by the Company until they become fully vested. As of June 30, 2022, there were no unvested shares issued under early-exercise provisions subject to repurchase by the Company.

#### 2018 Employee Stock Purchase Plan

In July 2018, the Company adopted the 2018 Employee Stock Purchase Plan (the "ESPP"). The ESPP permits participants to purchase common stock through payroll deductions of up to 20% of their eligible compensation. The Company's offering period begins in May and November of each year. As of June 30, 2022, an aggregate of 1,263,479 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, 2022, an additional 475,982 shares became available for future issuance under the ESPP.

#### **Stock Awards**

#### Stock Options

The Company's stock option activity during the six months ended June 30, 2022 was as follows:

	Options Outstanding	Weighted- Average Exercise Price	Weighted- Average Remaining Term	Aggregate Intrinsic Value (000's)
Balance at December 31, 2021	6,553,594	\$ 16.07		
Granted	2,527,579	\$ 20.40		
Exercised	(429,955)	\$ 8.18		
Forfeited and expired	(132,460)	\$ 18.90		
Balance at June 30, 2022	8,518,758	\$ 17.71	8.3	\$ 23,987
Vested and expected to vest at June 30, 2022	8,518,758	\$ 17.71	8.3	\$ 23,987
Exercisable at June 30, 2022	3,407,092	\$ 14.85	7.0	\$ 18,928



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, 2022 was \$5.1 million.

## Restricted Stock Units

The Company's restricted stock unit activity during the six months ended June 30, 2022 was as follows:

	Restricted Stock Units Outstanding	Weighted- Average Grant Date Fair Value			Aggregate Fair Value (000's)
Balance at December 31, 2021	—		—		
Granted	306,919	\$	20.02		
Vested	_				
Forfeited	(25,018)	\$	20.02		
Balance at June 30, 2022	281,901	\$	20.02	\$	5,643
Vested and expected to vest at June 30, 2022	281,901	\$	20.02	\$	5,643

#### Fair Value of Stock Awards

The Company utilizes the Black-Scholes option pricing model to value awards under its equity plans. 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 six months ended June 30, 2022 and 2021:

Stock Option Awards	2022	2021
Expected option term	6.0 years	6.0 years
Expected volatility	88%	87%
Risk free interest rate	2.2%	1.0%
Expected dividend yield	%	%

The weighted-average fair value of stock options awarded during the six months ended June 30, 2022 and 2021 was \$15.02 and \$11.31 per share, 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 options represents the period that 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 ESPP represents the term the awards are expected to be outstanding; (ii) Expected volatility - the expected volatility assumption is based on volatilities of a peer group of similar companies in the biotechnology industry whose share prices are publicly available; (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 e	ended June 30,	
	 2022		2021	 2022		2021
Included in research and development	\$ 3,681	\$	2,357	\$ 6,872	\$	4,170
Included in general and administrative	3,450		1,876	6,014		3,469
Total stock-based compensation expense	\$ 7,131	\$	4,233	\$ 12,886	\$	7,639

As of June 30, 2022, unrecognized stock-based compensation cost related to option awards, restricted stock units, and ESPP was \$68.3 million, \$5.2 million and \$1.5 million, respectively, which is expected to be recognized over a remaining weighted-average period of approximately 2.2 years, 3.7 years and 1.5 years, respectively.

#### **11. SUBSEQUENT EVENT**



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.

#### 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, 2021.

#### **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 rare 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, or NETs, CRN04777, which is in clinical development for congenital hyperinsulinism, or HI, 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 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 26,000 people in the United States suffer from acromegaly, and depending on surgical success, many 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 171,000 adults in the United States. Of these, approximately 19%, or 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. While still an orphan disease, NETs are the second most common gastrointestinal malignancy after colon cancer. 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 (NCCN) guidelines. In 2021, somatostatin peptide drugs accounted for approximately \$3.1 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 patie

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. The primary endpoint of both PATHFNDR studies will be 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. We expect topline data from both studies in 2023. We believe that, if successful, the two trials could support registration of paltusotine for all acromegaly patients who require pharmacotherapy, including untreated patients and those switching from other therapies.

We are also conducting a Phase 2 trial to assess the safety and pharmacokinetics of paltusotine in patients with NETs complicated by carcinoid syndrome. We expect topline data from this study in 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.

#### 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. We have 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 in September 2021 and announced positive topline data from the multiple ascending dose, or MAD, cohorts in March 2022. 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 the patients experience. We plan to initiate a Phase 2 clinical study of CRN04777 in patients with congenital HI upon the completion of ongoing discussions with global regulatory agencies.

The FDA has granted rare pediatric disease designation for CRN04777 for the treatment of congenital HI. In addition, the European Medicines Agency, or EMA, has granted orphan drug designation for CRN04777 for the treatment of congenital HI. We also expect CRN04777 can be broadly developed for the treatment of other diseases characterized by excess insulin secretion, including forms of syndromic hyperinsulinism.

#### CRN04894 (ACTH Antagonist)

CRN04894 is our investigational, oral, nonpeptide product candidate designed to antagonize ACTH, 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. 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. In August 2021, we announced positive topline data from the SAD cohorts of the Phase 1 study and in May 2022, we announced positive topline results from the MAD cohorts of the Phase 1 study. CRN04894 was well tolerated and demonstrated dose-dependent increases in CRN04894 plasma concentrations as well as 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. We plan to initiate clinical studies of CRN04894 in patients with Cushing's disease and CAH upon the completion of discussions with global regulatory agencies.

#### 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.

## 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.

#### **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 our drug discovery efforts and leverage our expertise in the evaluation of additional conditions including nonfunctional pituitary adenomas and polycystic kidney 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. Other than the Sanwa License with respect to the exclusive right to develop and commercialize paltusotine in Japan and the Radionetics License with respect to the exclusive right to our radiotherapeutics technology, we have retained worldwide rights to commercialize our product candidates and do not have any royalty obligations.

#### 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 ongoing COVID-19 global pandemic on our drug manufacturing, nonclinical activities, and clinical trials, expected timelines, and costs on an ongoing basis. In light of the COVID-19 pandemic, and consistent with the FDA's updated industry guidance for conducting clinical trials issued on March 18, 2020, and updated most recently on August 30, 2021, clinical trials may be deprioritized in favor of treating patients who have contracted the virus or to prevent the spread of the virus. 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, 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 preferred stock, and sales of our common stock. As of June 30, 2022, we had unrestricted cash, cash equivalents, and investment securities of \$408.5 million.

We have incurred cumulative net losses since our inception and, as of June 30, 2022, we had an accumulated deficit of \$352.3 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, all of our revenue has been derived from 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, 2022. 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 in 2021 were derived from the majority equity stake obtained in Radionetics pursuant to a Collaboration and License Agreement, under which Radionetics was granted an exclusive world-wide license to our radiotherapeutics technology platform and associated intellectual property for the development of radiotherapeutics and related radio-imaging agents.

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

On June 14, 2022, the Company and Sanwa, entered into a clinical supply agreement, or the Sanwa Clinical Supply Agreement, whereby the Company is responsible for manufacturing and supplying certain materials to Sanwa for specified activities under the Sanwa License. No purchases were made by Sanwa under the Sanwa Clinical Supply Agreement during the 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 2022 and 2021 related to the research and development of paltusotine, CRN04777, and CRN04894. 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 substantially 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 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 anticipate increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs associated with operating as a public company.

#### **Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which 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 Policies and Significant Judgments and Estimates" contained in our Annual Report on Form 10-K for the year ended December 31, 2021. Other than those changes discussed below made in connection with the Sanwa License during



the six months ended June 30, 2022, there have not been any material changes to the critical accounting policies discussed therein during the three and six months ended June 30, 2022.

We have generated revenue from licensing arrangements. We recognize revenues when, or as, the promised goods or services are transferred to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those services. To determine revenue recognition for licensing arrangements, we perform 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, we assess the goods or services promised within each contract, assess whether each promised good or service is distinct and identify those that are performance obligations. We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when, or as, the performance obligation is satisfied.

We have 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. At the initiation of an agreement, we analyze each unit of account within the contract to determine if the counterparty is a customer in the context of the unit of account.

We consider 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, and whether the license is functional or symbolic. We evaluate 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, we use 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, the estimated amount is included in the transaction price. Milestone payments that are not within our 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, we re-evaluate estimated variable consideration included in the transaction price and any related constraint and, as necessary, adjust 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.

We develop 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 we have applied significant judgment. We develop assumptions that require judgment to determine the standalone selling price for license-related performance obligations under the adjusted market assessment approach, which may include forecasted revenues, development timelines, discount rates and probabilities of success. We estimated the standalone selling price for the data exchange performance obligation 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, we recognize 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, we use 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, we evaluate the measure of progress each reporting period and, if necessary, adjust 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. Revenue is recorded proportionally as costs are incurred. We have used the cost-to-cost measure of progress because it best depicts the transfer of control to the customer which occurs as we incur 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. We use 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. We evaluate these cost estimates and the progress each reporting period and, as necessary, we adjust 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.

Although we do not expect our estimates to be materially different, if our estimates of the expected total costs and timing of certain activities differ from the actual status and timing of those activities, it could result in us reporting license revenues related to the data exchange that are too high or too low in any particular period.

Estimating the standalone selling price of the license performance obligation is affected by assumptions regarding a number of variables discussed above. While not expected, material changes in these initial assumptions can affect the value of license revenues. These inputs are subjective and generally require significant analysis and judgment to develop.

#### **Results of Operations**

#### Comparison of the three months ended June 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended June 30, 2022 and 2021 (in thousands):

	Three months	Dollar			
	2022		2021		Change
License revenues	\$ 439	\$	_	\$	439
Operating expenses:					
Research and development	32,995		20,487		12,508
General and administrative	10,489		5,602		4,887
Total operating expenses	43,484		26,089		17,395
Loss from operations	(43,045)		(26,089)		(16,956)
Other income (expense), net	670		(6)		676
Loss before equity method investment	 (42,375)		(26,095)		(16,280)
Loss on equity method investment			_		
Net loss	\$ (42,375)	\$	(26,095)	\$	(16,280)

*License revenues.* License revenues relate to the Sanwa License and totaled \$0.4 million for the three months ended June 30, 2022. There were no license revenues during the three months ended June 30, 2021.

*Research and development expenses.* Research and development expenses were \$33.0 million and \$20.5 million for the three months ended June 30, 2022 and 2021, respectively. The change was primarily due to increased spending on manufacturing and development activities of \$7.6 million associated with our clinical and nonclinical activities for paltusotine, CRN04777, CRN04894 and our other clinical and preclinical programs, an increase in personnel costs of \$3.9 million, and increased consulting and outside services of \$0.8 million.

*General and administrative expenses.* General and administrative expenses were \$10.5 million and \$5.6 million for the three months ended June 30, 2022 and 2021, respectively. The change was primarily due to an increase in personnel costs of \$3.1 million, increased legal and professional services expenses of \$0.6 million, increased consulting and outside services of \$0.9 million and increases in other corporate expenditures of \$0.3 million.

*Other income (expense).* Other income (expense), net was \$0.7 million and \$(6,000) for the three months ended June 30, 2022 and 2021, respectively. The change was primarily due to income generated by our investment securities.

#### Comparison of the six months ended June 30, 2022 and 2021

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2021 (in thousands):

	Six months er	Dollar			
	 2022	2021			Change
License revenues	\$ 3,570	\$	—	\$	3,570
Operating expenses:					
Research and development	61,247		38,071		23,176
General and administrative	19,195		10,936		8,259
Total operating expenses	80,442		49,007		31,435
Loss from operations	(76,872)		(49,007)		(27,865)
Other income (expense), net	880		11		869
Loss before equity method investment	(75,992)		(48,996)		(26,996)
Loss on equity method investment	(1,010)		—		(1,010)
Net loss	\$ (77,002)	\$	(48,996)	\$	(28,006)

*License revenues.* License revenues relate to the Sanwa License and totaled \$3.6 million for the six months ended June 30, 2022. There were no license revenues during the six months ended June 30, 2021.

*Research and development expenses.* Research and development expenses were \$61.2 million and \$38.1 million for the six months ended June 30, 2022 and 2021, respectively. The change was primarily due to increased spending on manufacturing and development activities of \$14.6 million associated with our clinical and nonclinical activities for paltusotine, CRN04777, CRN04894 and our other

clinical and preclinical programs, an increase in personnel costs of \$6.9 million, and increased consulting and outside services of \$1.5 million.

*General and administrative expenses.* General and administrative expenses were \$19.2 million and \$10.9 million for the six months ended June 30, 2022 and 2021, respectively. The change was primarily due to an increase in personnel costs of \$5.2 million, increased legal and professional services expenses of \$0.8 million, increased consulting and outside services of \$1.8 million and an increase in other corporate expenditures of \$0.4 million.

*Other income (expense).* Other income (expense), net was \$0.9 million and \$11,000 for the six months ended June 30, 2022 and 2021, respectively. The increase 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. As the Radionetics investment was recorded in the fourth quarter of the year ended December 31, 2021, there was no loss on equity method investment during the six months ended June 30, 2021.

#### **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, 2022, we had unrestricted cash, cash equivalents and investment securities of \$408.5 million and an accumulated deficit of \$352.3 million.

The following table provides information regarding our cash flows for the six months ended June 30, 2022 and 2021 (in thousands):

	Six months ended June 30,					
	2022		2021			
Net cash used in operating activities	\$ (41,519)	\$	(40,016)			
Net cash (used in) provided by investing activities	(217,655)		52,340			
Net cash provided by financing activities	120,772		73,360			
Net change in cash, cash equivalents and restricted cash	\$ (138,402)	\$	85,684			

*Operating Activities.* Net cash used in operating activities was \$41.6 million and \$40.0 million for the six months ended June 30, 2022 and 2021, respectively. The increase in cash used in operations was primarily attributable to the development and manufacturing activities associated with paltusotine, CRN04777, CRN04894, and our other clinical and preclinical programs, and higher personnel costs partially offset by the \$13.0 million upfront payment received upon the execution of the Sanwa License in February 2022, of which \$3.6 million was recognized as license revenues during the six months ended June 30, 2022. The 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 in Radionetics, and a \$20.5 million change in operating assets and liabilities. Net cash used in operating assets and liabilities, adjusted for \$8.4 million of noncash charges, primarily due to our net loss of \$49.0 million and a \$0.6 million increase in operating assets and liabilities, adjusted for \$8.4 million of noncash charges, primarily for stock-based compensation.

*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 outflow of funds of approximately \$217.7 million during the first six months of 2022, compared to net inflow of funds of approximately \$52.3 million during the comparable period of 2021.

*Financing activities.* Net cash provided by financing activities was \$120.8 million and \$73.4 million for the six months ended June 30, 2022 and 2021, respectively. The net cash provided by financing activities during 2022 and 2021 resulted from proceeds received from the sale of common stock in our underwritten follow-on offerings 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 of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could 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, including our option to exercise our warrant for the purchase of Radionetics stock.

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 having an aggregate offering price of up to \$75.0 million 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 19, 2019 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 Agents, 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 during the three and six months ended June 30, 2022.

On April 12, 2021, we completed an underwritten follow-on offering of 4,562,044 shares of our common stock at a price to the public of \$16.44 per share. Proceeds from the offering were approximately \$72.6 million, net of underwriting discounts and commissions and offering costs of \$2.4 million.

On July 28, 2021, we entered into a stock purchase agreement for the private placement of 851,306 shares of our common stock at a price of \$17.62 per share, or the Private Placement, which shares were issued on July 30, 2021. The Private Placement yielded net proceeds of \$15.0 million.

On August 10, 2021, we filed a universal shelf registration statement, or the 2021 Shelf Registration Statement, with the SEC for the future sale of an unlimited amount of common stock, preferred stock, debt securities, depositary shares, warrants and rights, and the resale of up to 851,306 shares by the investor who purchased shares in the Private Placement. The securities may be offered from time to time, separately or together, directly by us, by selling security holders, or through underwriters, dealers or agents at amounts, prices, interest rates and other terms to be determined at the time of the offering.

On October 21, 2021, we completed an underwritten follow-on offering of 8,712,400 shares of our common stock at a price to the public of \$19.80 per share. Proceeds from the offering were approximately \$162.0 million, net of underwriting discounts and commissions and offering costs of \$10.5 million.



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.

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.

The Company has no material off-balance sheet arrangements.

#### 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. We are therefore subject to fluctuations in foreign currency rates in connection with these agreements. We do not hedge our foreign currency exchange rate risk. 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 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 approximately (\$80,000) and (\$63,000) for the three and six months ended June 30, 2022, respectively, and (\$29,000) and (\$53,000) for the three and six months ended June 30, 2022, respectively.

As of June 30, 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

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations for the periods presented.

#### 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, 2022 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

There have been no 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, 2021.

#### 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

On August 10, 2021, we filed with the SEC a shelf registration statement (Registration No. 333-258694), which became immediately effective upon filing, and an accompanying prospectus. On August 12, 2022, we filed with the SEC a prospectus supplement 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 SVB Securities LLC and Cantor Fitzgerald & Co., or collectively, the Sales Agents, pursuant to the Sales Agreement dated August 13, 2019, by and between the Company and the Sales Agents. An opinion of Latham & Watkins LLP with respect to the validity of shares of the Company's common stock that may be offered and sold pursuant to such prospectus supplement and the accompanying prospectus is filed herewith as Exhibit 5.1.

## EXHIBIT INDEX

Exhibit		Incorporated by Reference				Filed
Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Herewith
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	S-1/A	333-225824	4.1	7/9/2018	
	Stock					
4.2	Amended and Restated Investor Rights Agreement, dated February	S-1	333-225824	4.2	6/22/2018	
	9, 2018, as amended, by and among the Registrant and certain of its					
	stockholders					
5.1	Opinion of Latham & Watkins LLP					Х
10.1#	Consulting Agreement, dated as of April 1, 2022, by and between	10-Q	001-38583	10.3	05/12/2022	
	Ajay Madan and the Registrant					
23.1	Consent of Latham & Watkins LLP (included in Exhibit 5.1)					Х
31.1	Certification of Chief Executive Officer pursuant to Rule					Х
	13(a)-14(a) and 15d-14(a), as adopted pursuant to Section 302 of					
	the Sarbanes Oxley Act of 2002					
31.2	Certification of Chief Financial Officer pursuant to Rule					Х
	<u>13(a)-14(a) and 15d-14(a), as adopted pursuant to Section 302 of</u>					
22.1*	the Sarbanes Oxley Act of 2002					V
32.1*	<u>Certification of Chief Executive Officer and Chief Financial</u> Officer pursuant 18. U.S.C. Section 1350, as adopted pursuant to					Х
	Section 906 of the Sarbanes Oxley Act of 2002					
101.INS	Inline XBRL Instance Document – the instance document does not					Х
101.1115	appear in the Interactive Data File because its XBRL tags are					Λ
	embedded within the inline XBRL document					
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					Х
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase					X
TOTIONE	Document.					21
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					Х
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase					X
191.1112	Document					<u> </u>
104	Cover Page Interactive Data File (formatted as inline XBRL and					Х
	contained in Exhibit 101)					<u> </u>

# 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.**

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

R. Scott Struthers, Ph.D.

President and Chief Executive Officer (Principal executive officer)

By: /s/ Marc J.S. Wilson

Marc J.S. Wilson

Chief Financial Officer (Principal financial and accounting officer)

34

Date: August 12, 2022

Date: August 12, 2022

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FIRM / AFFILIATE OFFICES

Austin Milan Beijing Munich Boston New York Brussels Orange County Century City Paris Chicago Riyadh Dubai San Diego Düsseldorf San Francisco Frankfurt Seoul Hamburg Shanghai Hong Kong Silicon Valley Houston Singapore London Tel Aviv Los Angeles Tokyo Madrid Washington, D.C.

August 12, 2022

Crinetics Pharmaceuticals, Inc. 10222 Barnes Canyon Road, Bldg. #2 San Diego, CA 92121

#### Re: <u>Registration Statement on Form S-3; Shares of Common Stock, par value \$0.001 per share, having an aggregate offering price of up to</u> <u>\$150,000,000</u>

To the addressees set forth above:

We have acted as special counsel to Crinetics Pharmaceuticals, Inc., a Delaware corporation (the "*Company*"), in connection with the sale through SVB Securities LLC ("*SVB Leerink*") and Cantor Fitzgerald & Co. ("*Cantor*") as the sales agents from time to time by the Company of shares (the "*Shares*") of common stock of the Company, par value \$0.001 per share (the "*Common Stock*"), having an aggregate offering price of up to \$150,000,000, to be issued pursuant to a registration statement on Form S-3 under the Securities Act of 1933, as amended (the "*Act*") filed by the Company with the Securities and Exchange Commission (the "*Commission*") on August 10, 2021 (the "*Registration Statement*"), the base prospectus included in the Registration Statement (the "*Base Prospectus*") and prospectus supplement dated August 12, 2022 filed with the Commission pursuant to Rule 424(b) under the Act (together with the Base Prospectus, the "*Prospectus*"), and that certain Sales Agreement, dated as of August 13, 2019, by and among the Company and SVB Leerink and Cantor (the "*Sales Agreement*").

This opinion is being furnished in connection with the requirements of Item 601(b)(5) of Regulation S-K under the Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or the Prospectus, other than as expressly stated herein with respect to the issue of the Shares.

As such counsel, we have examined such matters of fact and questions of law as we have considered appropriate for purposes of this letter. With your consent, we have relied upon certificates and other assurances of officers of the Company and others as to factual matters without having independently verified such factual matters.

## LATHAM&WATKINSLLP

We are opining herein as to the General Corporation Law of the State of Delaware (the "DGCL"), and we express no opinion with respect to any other laws.

Subject to the foregoing and the other matters set forth herein, it is our opinion that, as of the date hereof, when the Shares shall have been duly registered on the books of the transfer agent and registrar therefor in the name or on behalf of the purchasers, and have been issued by the Company against payment therefor (not less than par value) in the circumstances contemplated by the Sales Agreement, the issue and sale of the Shares will have been duly authorized by all necessary corporate action of the Company, and the Shares will be validly issued, fully paid and nonassessable. In rendering the foregoing opinion, we have assumed that (i) the Company will comply with all applicable notice requirements regarding uncertificated shares provided in the DGCL and (ii) upon the issue of any of the Shares, the total number of shares of Common Stock issued and outstanding will not exceed the total number of shares of Common Stock that the Company is then authorized to issue under its Amended and Restated Certificate of Incorporation.

This opinion is for your benefit in connection with the Registration Statement and may be relied upon by you and by persons entitled to rely upon it pursuant to the applicable provisions of the Act. We consent to your filing this opinion as an exhibit to the Company's Form 10-Q dated August 12, 2022, and to the reference to our firm in the Prospectus under the heading "Legal Matters." In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the Commission thereunder.

Sincerely,

/s/ Latham & Watkins LLP

#### 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 12, 2022

/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 12, 2022

/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, 2022 (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 12, 2022

#### **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, 2022 (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 12, 2022