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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

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

For the Transition Period From _____ to

Commission File No. 001-36913

KemPharm, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware **(State or Other Jurisdiction of Incorporation or Organization)**	**20-5894398** **(I.R.S. Employer Identification No.)**
1180 Celebration Boulevard, Suite 103, Celebration, FL **(Address of Principal Executive Offices)**	**34747** **(Zip Code)**

(321) 939-3416
(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address, and Former Fiscal Year if Changed Since Last Report)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	KMPH	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

Total shares of common stock outstanding as of November 8, 2022: 34,504,862

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KEMPHARM, INC.
FORM 10-Q

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements regarding future events and our future results that are subject to the safe harbors created under the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements relate to future events or our future financial performance. We generally identify forward-looking statements by terminology such as "may," "will," "would," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "assume," "intend," "potential," "continue" or other similar words or the negative of these terms. We have based these forward-looking statements largely on our current expectations about future events and financial trends that we believe may affect our business, financial condition and results of operations. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in Part II, Item 1A. "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 31, 2022. Accordingly, you should not place undue reliance upon these forward-looking statements. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur, the timing of events and circumstances and actual results could differ materially from those anticipated in the forward-looking statements. Forward-looking statements contained in this report include, but are not limited to, statements about:

- *the progress of, outcome or and timing of any regulatory approval for any of our product candidates and the expected amount or timing of any payment related thereto under any of our collaboration agreements;*
- *the progress of, timing of and expected amount of expenses associated with our research, development and commercialization activities;*
- *our ability to raise additional funds on commercially reasonable terms, or at all, in order to support our continued operations;*
- *the sufficiency of our cash resources to fund our operating expenses and capital investment requirements for any period;*
- *the expected timing of our clinical trials for our product candidates and the availability of data and results of those trials;*
- *our expectations regarding federal, state and foreign regulatory requirements;*
- *the potential therapeutic benefits and effectiveness of our products and product candidates;*
- *the size and characteristics of the markets that may be addressed by our products and product candidates;*
- *our intention to seek to establish, and the potential benefits to us from, any strategic collaborations or partnerships for the development or sale of our products and product candidates;*
- *our expectations as to future financial performance, expense levels and liquidity sources;*
- *the timing of commercializing our products and product candidates, if approved; and*
- *other factors discussed elsewhere in this report.*

The forward-looking statements made in this report relate only to events as of the date on which the statements are made. We have included or made reference to important factors in the cautionary statements included in this report, particularly in the section entitled "Risk Factors" where we make reference to Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 31, 2022, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. Except as required by law, we do not assume any intent to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events or circumstances or otherwise.

NOTE REGARDING COMPANY REFERENCE

Unless the context otherwise requires, we use the terms "KemPharm," "Company," "we," "us" and "our" in this Quarterly Report on Form 10-Q to refer to KemPharm, Inc. We have proprietary rights to a number of trademarks used in this Quarterly Report on Form 10-Q that are important to our business, including KemPharm, LAT and the KemPharm logo. All other trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Quarterly Report on Form 10-Q are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

PART I — FINANCIAL INFORMATION

ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

KEMPHARM, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and par value amounts)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 70,059	$ 112,346
Short-term investments	5,832	—
Accounts and other receivables	6,583	1,528
Prepaid expenses and other current assets	2,659	1,182
Total current assets	85,133	115,056
Inventories	596	—
Property and equipment, net	852	884
Operating lease right-of-use assets	1,068	1,141
Long-term investments	31,463	15,422
Other long-term assets	439	438
Total assets	$ 119,551	$ 132,941
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,279	$ 3,038
Current portion of operating lease liabilities	474	356
Current portion of discount and rebate liabilities	2,825	—
Other current liabilities	853	836
Total current liabilities	8,431	4,230
Line of credit payable	12,800	—
Derivative and warrant liability	35	330
Operating lease liabilities, less current portion	956	1,232
Discount and rebate liabilities, less current portion	3,509	—
Other long-term liabilities	26	31
Total liabilities	25,757	5,823
Commitments and contingencies (Note D)		
Stockholders’ equity:		
Preferred stock:		
Undesignated preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 2022 or December 31, 2021	—	—
Common stock, $0.0001 par value, 250,000,000 shares authorized, 35,411,097 shares issued and 34,501,144 shares outstanding as of September 30, 2022; 35,325,801 shares issued and 35,005,640 shares outstanding as of December 31, 2021	3	4
Additional paid-in capital	400,677	396,957
Treasury stock, at cost	(7,536)	(2,814)
Accumulated deficit	(299,551)	(267,029)
Accumulated other comprehensive income	201	—
Total stockholders' equity	93,794	127,118
Total liabilities and stockholders' equity	$ 119,551	$ 132,941

See accompanying notes to unaudited condensed consolidated financial statements

KEMPHARM, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Revenue, net	$ 2,874	$ 1,965	$ 8,139	$ 26,068
Operating expenses:				
Cost of revenue	141	0	200	2,000
Research and development	5,385	2,239	13,262	7,352
General and administrative	3,974	1,948	10,266	6,145
Acquired in-process research and development	—	—	17,663	—
Total operating expenses	9,500	4,187	41,391	15,497
(Loss) income from operations	(6,626)	(2,222)	(33,252)	10,571
Other (expense) income:				
Loss on extinguishment of debt	—	—	—	(16,096)
Interest expense related to amortization of debt issuance costs and discount	—	—	—	(150)
Interest expense on principal	(124)	(6)	(165)	(221)
Fair value adjustment related to derivative and warrant liability	22	332	295	(92)
Interest and other (expense) income, net	79	137	(152)	136
Total other (expense) income	(23)	463	(22)	(16,423)
Loss before income taxes	(6,649)	(1,759)	(33,274)	(5,852)
Income tax benefit	33	—	752	—
Net loss	$ (6,616)	$ (1,759)	$ (32,522)	$ (5,852)
Deemed dividend	—	—	—	(54,342)
Net loss attributable to common stockholders	$ (6,616)	$ (1,759)	$ (32,522)	$ (60,194)
Basic and diluted net loss per share of common stock:				
Net loss attributable to common stockholders	$ (0.19)	$ (0.05)	$ (0.94)	$ (2.16)
Weighted average number of shares of common stock outstanding:				
Basic and diluted	34,494,702	35,217,953	34,482,791	27,904,711

See accompanying notes to unaudited condensed consolidated financial statements

KEMPHARM, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Net loss attributable to common stockholders	$ (6,616)	$ (1,759)	$ (32,522)	$ (60,194)
Other comprehensive income:				
Foreign currency translation adjustment	201	—	201	—
Other comprehensive income	201	—	201	—
Comprehensive loss	$ (6,415)	$ (1,759)	$ (32,321)	$ (60,194)

See accompanying notes to unaudited condensed consolidated financial statements

KEMPHARM, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands)

	Undesignated Preferred Stock	Common Stock	Additional Paid-in Capital	Treasury Stock, at cost	Accumulated Deficit	Other Comprehensive Income	Total Stockholders' Equity
Balance as of January 1, 2022	$ —	$ 4	$ 396,957	$ (2,814)	$ (267,029)	$ —	$ 127,118
Net loss	—	—	—	—	(1,864)	—	(1,864)
Stock-based compensation expense	—	—	918	—	—	—	918
Shares repurchased as part of the Share Repurchase Program	—	(1)	—	(4,722)	—	—	(4,723)
Issuance of common stock in exchange for consulting services	—	—	50	—	—	—	50
Balance as of March 31, 2022	$ —	$ 3	$ 397,925	$ (7,536)	$ (268,893)	$ —	$ 121,499
Net loss	—	—	—	—	(24,042)	—	(24,042)
Stock-based compensation expense	—	—	1,510	—	—	—	1,510
Issuance of common stock in exchange for consulting services	—	—	50	—	—	—	50
Issuance of common stock as part of the Employee Stock Purchase Plan	—	—	216	—	—	—	216
Balance as of June 30, 2022	$ —	$ 3	$ 399,701	$ (7,536)	$ (292,935)	$ —	$ 99,233
Net loss	—	—	—	—	(6,616)	—	(6,616)
Stock-based compensation expense	—	—	911	—	—	—	911
Issuance of common stock in exchange for consulting services	—	—	65	—	—	—	65
Other comprehensive income	—	—	—	—	—	201	201
Balance as of September 30, 2022	$ —	$ 3	$ 400,677	$ (7,536)	$ (299,551)	$ 201	$ 93,794

See accompanying notes to unaudited condensed consolidated financial statements

KEMPHARM, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY, CONTINUED
(in thousands)

	Preferred Stock							
	Series A Convertible Preferred Stock	Series B-1 Convertible Preferred Stock	Series B-2 Convertible Preferred Stock	Undesignated Preferred Stock	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance as of January 1, 2021	$ —	$ —	$ —	$ —	$ 0	$ 192,062	$ (258,474)	$ (66,412)
Net loss	—	—	—	—	—	—	(10,296)	(10,296)
Stock-based compensation expense	—	—	—	—	—	675	—	675
Issuance of common stock in connection with Public Offering, net of discounts and commissions	—	—	—	—	1	49,284	—	49,285
Issuance of common stock in connection with the exercise of warrants in the Inducement Transaction, net of discounts and commissions	—	—	—	—	1	40,390	—	40,391
Issuance of common stock in connection with the exercise of common stock warrants	—	—	—	—	—	25,593	—	25,593
Fair value of warrants issued in connection with the Exchange Agreement	—	—	—	—	—	15,990	—	15,990
Fair value of Series B-2 Preferred Stock issued in accordance with the Exchange Agreement	—	—	29,056	—	—	—	—	—
Issuance of common stock as a result of Series B-2 Preferred Stock conversion	—	—	(29,056)	—	1	29,055	—	29,056
Fair value of warrants issued in connection with the Inducement Transaction	—	—	—	—	—	38,437	—	38,437
Deemed dividend related the Inducement Transaction	—	—	—	—	—	(37,444)	—	(37,444)
Offering expenses charged to equity	—	—	—	—	—	(1,106)	—	(1,106)
Issuance of common stock in exchange for consulting services	—	—	—	—	—	82	—	82
Balance as of March 31, 2021	$ —	$ —	$ —	$ —	$ 3	$ 353,018	$ (268,770)	$ 84,251
Net income	—	—	—	—	—	—	6,203	6,203
Stock-based compensation expense	—	—	—	—	—	318	—	318
Issuance of common stock in connection with the exercise of warrants in the June 2021 Inducement Transaction, net of discounts and commissions	—	—	—	—	—	35,455	—	35,455
Issuance of common stock in connection with the exercise of common stock warrants	—	—	—	—	—	4,191	—	4,191
Fair value of warrants issued in connection with the June 2021 Inducement Transaction	—	—	—	—	—	17,089	—	17,089
Deemed dividend related the June 2021 Inducement Transaction	—	—	—	—	—	(16,898)	—	(16,898)
Offering expenses charged to equity	—	—	—	—	—	(18)	—	(18)
Issuance of common stock in exchange for consulting services	—	—	—	—	—	72	—	72
Balance as of June 30, 2021	$ —	$ —	$ —	$ —	$ 3	$ 393,227	$ (262,567)	$ 130,663
Net loss	—	—	—	—	—	—	(1,759)	(1,759)
Stock-based compensation expense	—	—	—	—	—	620	—	620
Issuance of common stock in connection with the exercise of warrants in the June 2021 Inducement Transaction, net of discounts and commissions	—	—	—	—	1	1,104	—	1,105
Issuance of common stock in connection with the exercise of	—	—	—	—	—	1,035	—	1,035

common stock warrants								
Issuance of common stock in exchange for consulting services	—	—	—	—	—	73	—	73
Balance as of September 30, 2021	$ —	$ —	$ —	$ —	$ 4	$ 396,059	$ (264,326)	$ 131,737

See accompanying notes to unaudited condensed consolidated financial statements

KEMPHARM, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Nine months ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (32,522)	$ (5,852)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Loss on extinguishment of debt	—	16,096
Stock-based compensation expense	3,339	1,613
Non-cash interest expense	—	8
Amortization of debt issuance costs and debt discount	—	150
Depreciation and amortization expense	644	193
Fair value adjustment related to derivative and warrant liability	(295)	92
Fair value adjustment related to investments	634	—
Loss on sublease and disposal of property and equipment	9	76
Consulting fees paid in common stock	165	227
Acquired in-process research and development	17,663	—
Change in assets and liabilities:		
Accounts and other receivables	(4,646)	960
Prepaid expenses and other assets	(1,196)	(1,366)
Inventories	280	—
Operating lease right-of-use assets	82	88
Accounts payable and accrued expenses	1,262	(1,891)
Discount and rebate liabilities	858	—
Operating lease liabilities	(160)	(241)
Other liabilities	(372)	1,134
Net cash (used in) provided by operating activities	(14,255)	11,287
Cash flows from investing activities:		
Acquisitions, net	(14,090)	—
Purchases of property and equipment	(59)	(85)
Purchases of investments	(23,832)	—
Maturities of investments	1,325	—
Net cash used in investing activities	(36,656)	(85)
Cash flows from financing activities:		
Proceeds from issuance of debt	12,800	—
Proceeds from Public Offering, net of discounts and commissions	—	49,285
Proceeds from January 2021 Inducement Transaction, net of discounts and commissions	—	41,384
Proceeds from June 2021 Inducement Transaction, net of discounts and commissions	—	36,751
Proceeds from insurance financing arrangements	1,273	—
Proceeds from Employee Stock Purchase Plan	216	—
Payments of principal on insurance financing arrangements	(876)	—
Payment to repurchase shares as part of the Share Repurchase Program	(4,723)	—
Payment of offering costs	(68)	(1,299)
Repayment of principal on finance lease liabilities	(13)	(156)
Payment of debt issuance costs	—	(2,881)
Repayment of principal on convertible notes	—	(37,924)
Net proceeds from exercise of common stock warrants	—	30,819
Net cash provided by financing activities	8,609	115,979
Effect of exchange rate changes on cash and cash equivalents	15	—
Net (decrease) increase in cash and cash equivalents	(42,287)	127,181
Cash and cash equivalents, beginning of period	112,346	4,322
Cash and cash equivalents, end of period	$ 70,059	$ 131,503
Supplemental cash flow information:		
Cash paid for interest	$ 165	$ 213
Facility Notes principal converted to Series B-2 Preferred Stock	—	31,477
Amounts due for property and equipment included in accounts payable and accrued expenses	—	—
Amounts due for deferred offering costs included in accounts payable and accrued expenses	—	70
Fair value of warrants issued to underwriters in connection with Public Offering	—	3,485

See accompanying notes to unaudited condensed consolidated financial statements.

KEMPHARM, INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

A. Description of Business, Basis of Presentation and Significant Transactions

Organization

KemPharm, Inc. (the "Company") is a biotechnology company focused on the discovery, development and commercialization of novel treatments for rare central nervous system ("CNS") and neurodegenerative diseases, lysosomal storage disorders and related treatment areas. The Company has a diverse product portfolio, combining a clinical-stage pipeline with new drug application ("NDA") stage and commercial assets. The Company's pipeline includes arimoclomol, an orally-delivered, first-in-class investigational product candidate for Niemann-Pick disease type C ("NPC"), and KP1077, which the Company is developing as a treatment for idiopathic hypersomnia ("IH"), a rare neurological sleep disorder, and narcolepsy. In addition, the U.S. Food and Drug Administration ("FDA") has approved AZSTARYS®, formally referred to as KP415, a once-daily treatment for attention deficit hyperactivity disorder ("ADHD") in patients age six years and older containing the Company's prodrug, serdexmethylphenidate ("SDX"), which is being commercialized by Corium, Inc. ("Corium"), an affiliate of Gurnet Point Capital, L.P., in the U.S. The FDA has also approved APADAZ®, an immediate-release combination product containing benzhydrocodone, the Company's prodrug of hydrocodone, and acetaminophen, which is being commercialized by KVK-Tech, Inc. in the U.S.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. Accordingly, they do not include all of the information and related notes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included in the accompanying financial statements. Operating results for the three and nine months ended September 30, 2022, are not necessarily indicative of the results that may be expected for the full year ending December 31, 2022.

This interim information should be read in conjunction with the audited financial statements included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the Securities and Exchange Commission (“SEC”) on March 31, 2022.

Basis of Presentation

The Company prepared the financial statements in accordance with U.S. GAAP and the rules and regulations of the United States Securities and Exchange Commission (the "SEC") and, in the Company's opinion, reflect all adjustments, including normal recurring items that are necessary.

Arimoclomol Acquisition

On May 15, 2022, the Company and KemPharm Denmark A/S ("KemPharm DK"), a newly formed Danish company and wholly-owned subsidiary of KemPharm, Inc., entered into an asset purchase agreement (the "Arimoclomol Purchase Agreement") with Orphazyme A/S in restructuring, a Danish public limited liability company ("Orphazyme"). The Arimoclomol Purchase Agreement closed on May 31, 2022. Under the terms of the Arimoclomol Purchase Agreement, KemPharm DK purchased all of the assets and operations of Orphazyme related to arimoclomol and settled all of Orphazyme's actual outstanding liabilities to its creditors with a cash payment of $12.8 million. In addition, KemPharm DK agreed to assume an estimated reserve liability of $5.2 million related to revenue generated from Orphazyme's Early Access Program in France.

The Company accounted for the arimoclomol acquisition as an asset acquisition as the majority of the value of the assets acquired related to the arimoclomol acquired in-process research and development ("IPR&D") asset. The intangible asset associated with IPR&D relates to arimoclomol. The estimated fair value of $17.7 million was determined using the excess earnings valuation method, a variation of the income valuation approach. The excess earnings valuation method estimates the value of an intangible asset equal to the present value of the incremental after-tax cash flows attributable to that intangible asset over its remaining economic life. Some of the more significant assumptions utilized in our asset valuations included the estimated i) net cash flows, including net revenues, cost of sales, research and development and other operating expenses, ii) the potential regulatory and commercial success rates, iii) market penetration and pricing assumptions, and iv) tax rates, and were based on our most recent strategic plan. The fair value using the excess earnings valuation method was determined using an estimated weighted average cost of capital of 42%, which reflects the risks inherent in future cash flow projections and represents a rate of return that a market participant would expect for this asset. This fair value measurement was based on significant inputs not observable in the market and thus represent Level 3 fair value measurement.

In accordance with Accounting Standards Codification, Subtopic 730-10-25, *Accounting for Research and Development Costs*, the up-front payments to acquire a new drug compound, as well as future milestone payments when paid or payable, are immediately expensed as acquired IPR&D in transactions other than a business combination provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use. Therefore, the portion of the purchase price that was allocated to the IPR&D assets acquired was immediately expensed. Other assets acquired and liabilities assumed, were recorded at fair value. The company also recorded a $0.7 million income tax benefit for the three and nine months ended September 30, 2022, related to research and development credits that are expected to be realized from the local jurisdiction in Denmark.

The following represents the consideration paid and purchase price allocation for the acquisition of arimoclomol (in thousands):

Cash	$	12,800
Assumed reserve liability		5,200
Total consideration	**$**	**18,000**
Total consideration	$	18,000
Direct transaction costs associated with the acquisition (1)		1,290
Total purchase price to be allocated	**$**	**19,290**
Property and equipment, inventory and assembled workforce acquired	$	1,627
IPR&D (2)		17,663
Total allocated purchase price	**$**	**19,290**

(1) As a result of the asset acquisition accounting, the transaction costs associated with the acquisition should be included in the costs of the assets acquired and allocated amongst qualifying assets using the relative fair value basis. The transaction costs primarily included financial advisor fees and legal expenses.
(2) The primary asset acquired, the IPR&D asset, was expensed and the allocated transaction related costs were included with and expensed with this asset.

Underwriting Agreement

On January 8, 2021, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Roth Capital Partners, LLC (the "Underwriter" or "Roth"), to issue and sell 6,765,463 shares of common stock of the Company, pre-funded warrants to purchase 926,844 shares of common stock and warrants to purchase 7,692,307 shares of common stock at an exercise price per share of $6.50 in an underwritten public offering (the "Public Offering") pursuant to a registration statement on Form S-1 (File No. 333-250945) and a related prospectus, in each case filed with the Securities and Exchange Commission (the "SEC"). The offering price to the public was $6.50 per share of common stock and accompanying warrant, representing a public offering price of $6.4999 per share of common stock and $0.0001 per related warrant. In addition, the Company granted the Underwriter an option to purchase, for a period of 45 days, up to an additional 1,153,846 shares of the Company's common stock and/or warrants to purchase up to an additional 1,153,846 shares of the Company's common stock.

On January 8, 2021, the Underwriter exercised its over-allotment option, in part, for warrants to purchase 754,035 shares of the Company's common stock. Further on February 1, 2021, the Underwriter again exercised its over-allotment option to purchase 374,035 shares of common stock.

On January 12, 2021, the Company closed the Public Offering. The aggregate gross proceeds to the Company from the Public Offering, including over-allotment, totaled approximately $52.4 million, before deducting underwriting discounts and commissions and offering expenses payable by the Company.

On January 25, 2022, the Company filed an amendment to the registration statement on Form S-1 (File No. 333-250945) on Form S-3 covering the issuance of the shares of our common stock issuable upon the exercise of the warrants issued in the Public Offering and remaining unexercised as of the date of the amendment, which was declared effective on February 1, 2022.

Listing on the Nasdaq Stock Market

On January 7, 2021, the Company's common stock was approved for listing on the Nasdaq Capital Market. The Company's common stock began trading on the Nasdaq Capital Market on January 8, 2021, under the ticker symbol "KMPH".

On October 19, 2021, the Company announced that its shares of common stock were approved for listing to the Nasdaq Global Select Market. Trading on the Nasdaq Global Select Market commenced effective with the open of business on October 19, 2021, under the Company's ticker symbol, "KMPH". The Company was previously listed on the Nasdaq Capital Market, following its uplisting to the exchange in January 2021.

Entry into 2021 ATM Agreement

On July 2, 2021, the Company entered into an equity distribution agreement (the "2021 ATM Agreement") with JMP Securities LLC ("JMP") and RBC Capital Markets, LLC ("RBCCM") under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock having an aggregate offering price of up to $75.0 million through JMP and RBCCM as its sales agents. The issuance and sale, if any, of common stock by the Company under the 2021 ATM Agreement will be made pursuant to a registration statement on Form S-3. JMP and RBCCM may sell the common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act of 1933, as amended. JMP and RBCCM will use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay JMP and RBCCM a commission equal to 3.0% in the aggregate of the gross sales proceeds of any common stock sold through JMP and RBCCM under the 2021 ATM Agreement. The Company filed a registration statement on Form S-3 covering the sale of the shares of its common stock up to $350.0 million, $75.0 million of which was allocated to the sales of the shares of common stock issuable under the 2021 ATM Agreement, which was declared effective on July 12, 2021. As of September 30, 2022, no shares have been issued or sold under the 2021 ATM Agreement.

Share Repurchase Program

On December 20, 2021, the Company initiated a share repurchase program (the "Share Repurchase Program") pursuant to which the Company may repurchase up to $50 million of shares of its common stock through December 31, 2023. Capital allocation to the Share Repurchase Program will be based on a variety of factors, including our business results, the receipt of royalties and sales milestones under the AZSTARYS License Agreement (refer to Note B), and potentially other sources of non-dilutive capital that may become available to the Company. Repurchases will be made in compliance with Rule 10b-18 of the Securities Exchange Act of 1934, as amended, subject to a variety of factors, including the market price of the Company's common stock, general market and economic conditions and applicable legal requirements. The exact number of shares to be repurchased by the Company is not guaranteed and the program may be suspended, modified, or discontinued at any time without prior notice. The Company does not currently intend to retire the repurchased treasury shares, rather all repurchased treasury shares will remain authorized but unissued. As of September 30, 2022, the Company has repurchased 909,953 shares of its common stock for approximately $7.5 million under the Share Repurchase Program.

B. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

On an ongoing basis, the Company evaluates its estimates and assumptions, including those related to revenue recognition, the useful lives of property and equipment, the recoverability of long-lived assets, the incremental borrowing rate for leases, and assumptions used for purposes of determining stock-based compensation, income taxes, the fair value of long-term investments and the fair value of the derivative and warrant liability, discount and rebate liabilities, among others. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable, the results of which form the basis for making judgments about the carrying value of assets and liabilities.

Revenue Recognition

The Company commenced recognizing revenue in accordance with the provisions of ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), starting January 1, 2018.

Arrangements with Multiple-Performance Obligations

From time to time, the Company enters into arrangements for research and development, manufacturing and/or commercialization services. Such arrangements may require the Company to deliver various rights, services, including intellectual property rights/licenses, research and development services, and/or commercialization services. The underlying terms of these arrangements generally provide for consideration to the Company in the form of nonrefundable upfront license fees, development and commercial performance milestone payments, royalty payments, consulting fees and/or profit sharing.

In arrangements involving more than one performance obligation, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects the Company's best estimate of what the selling price would be if the deliverable was regularly sold by the Company on a stand-alone basis or using an adjusted market assessment approach if selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control of the related goods or services is transferred. Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. Should there be royalties, the Company utilizes the sales and usage-based royalty exception in arrangements that resulted from the license of intellectual property, recognizing revenues generated from royalties or profit sharing as the underlying sales occur.

Licensing Agreements

The Company enters into licensing agreements with licensees that fall under the scope of ASC 606.

The terms of the Company's licensing agreements typically include one or more of the following: (i) upfront fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; and (iii) royalties on net sales of licensed products. Each of these payments may result in licensing revenues.

As part of the accounting for these agreements, the Company must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. Generally, the estimation of the stand-alone selling price may include such estimates as, independent evidence of market price, forecasted revenues or costs, development timelines, discount rates, and probability of regulatory success. The Company evaluates each performance obligation to determine if they can be satisfied at a point in time or over time, and it measures the services delivered to the licensee which are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated input component and, therefore revenue or expense recognized, would be recorded as a change in estimate. In addition, variable consideration (e.g., milestone payments) must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Up-front Fees: If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time.

Milestone Payments: At the inception of each arrangement that includes milestone payments (variable consideration), the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the licensee's control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of milestones that are within its or the licensee's control, such as operational developmental milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and earnings in the period of adjustment. Revisions to the Company's estimate of the transaction price may also result in negative licensing revenues and earnings in the period of adjustment.

AZSTARYS License Agreement

In September 2019, the Company entered into a Collaboration and License Agreement (the "AZSTARYS License Agreement") with Commave Therapeutics SA, an affiliate of Gurnet Point Capital ("Commave"). Under the AZSTARYS License Agreement, the Company granted to Commave an exclusive, worldwide license to develop, manufacture and commercialize the Company's product candidates containing SDX and d-methylphenidate ("d-MPH"), including AZSTARYS, KP484, and, at the option of Commave, KP879, KP922 or any other product candidate developed by the Company containing SDX and developed to treat ADHD or any other CNS disorder (the "Additional Product Candidates" and, collectively with AZSTARYS and KP484, the "Licensed Product Candidates"). Pursuant to the AZSTARYS License Agreement, Commave (i) paid the Company an upfront payment of $10.0 million; (ii) agreed to pay milestone payments of up to $63.0 million upon the occurrence of specified regulatory milestones related to AZSTARYS and KP484; (iii) agreed to pay additional payments of up to $420.0 million upon the achievement of specified U.S. sales milestones; and (iv) has agreed to pay the Company quarterly, tiered royalty payments ranging from a percentage in the high single digits to the mid-twenties of Net Sales (as defined in the AZSTARYS License Agreement) in the United States and a percentage in the low to mid-single digits of Net Sales in each country outside the United States, in each case subject to specified reductions under certain conditions as described in the AZSTARYS License Agreement. Commave is obligated to make such royalty payments on a product-by-product basis until expiration of the royalty term for the applicable product.

In April 2021, the Company entered into Amendment No. 1 to the AZSTARYS Amendment (the "AZSTARYS Amendment"). Pursuant to the AZSTARYS Amendment, the Company and Commave agreed to modify the compensation terms of the AZSTARYS License Agreement. Pursuant to the AZSTARYS Amendment, Commave paid the Company $10.0 million in connection with the entry into the AZSTARYS Amendment as a result of the regulatory approval of AZSTARYS in the United States which occurred on March 2, 2021. Commave also paid the Company $10.0 million following the receipt of the scheduling determination of the compound SDX by the U.S. Drug Enforcement Agency (the "DEA"), which occurred on May 7, 2021. In addition, the AZSTARYS Amendment increased the total remaining future regulatory and sales milestone payments related to AZSTARYS to up to an aggregate of $590.0 million in payments upon the occurrence of specified regulatory milestones related to AZSTARYS and upon the achievement of specified U.S. net sales milestones. Further, under the AZSTARYS Amendment, Commave agreed to pay the Company quarterly, tiered royalty payments that are calculated from a base royalty rate percentage in the high single digits to the mid-twenties of net sales in the United States, subject to adjustment based on annual net sales, and a percentage in the low to mid-single digits of Net Sales in each country outside the United States, in each case subject to specified reductions under certain conditions, including with respect to the final approval label, as described in the AZSTARYS License Agreement. Commave is obligated to make such royalty payments on a product-by-product basis until expiration of the royalty term for the applicable product.

Pursuant to the AZSTARYS Amendment, Commave and the Company also agreed to modify Commave's right of first refusal ("ROFR") such that the Company's product candidate, KP922, is no longer subject to Commave' ROFR to acquire, license or commercialize any Additional Product Candidate. Commave's ROFR shall only apply to any Additional Product Candidate which contains SDX, with such ROFR expiring upon the acceptance of an NDA for such Additional Product Candidate containing SDX.

Commave also agreed to be responsible for and reimburse the Company for all of the development, commercialization and regulatory expenses incurred on the licensed products, subject to certain limitations as set forth in the AZSTARYS License Agreement. As part of this agreement the Company is obligated to perform consulting services on behalf of Commave related to the licensed products. For these consulting services, Commave has agreed to pay the Company a set rate per hour on any consulting services performed on behalf of Commave for the benefit of the licensed products.

In accordance with the terms of the Company's March 20, 2012 Termination Agreement with Aquestive Therapeutics (formerly known as MonoSol Rx, LLC), Aquestive Therapeutics has the right to receive an amount equal to 10% of any royalty or milestone payments made to the Company related to AZSTARYS, KP484, KP879 or KP1077 under the AZSTARYS License Agreement.

The AZSTARYS License Agreement is within the scope of ASC 606, as the transaction represents a contract with a customer where the participants function in a customer / vendor relationship and are not exposed equally to the risks and rewards of the activities contemplated under the AZSTARYS License Agreement. Using the concepts of ASC 606, the Company identified the grant of the exclusive, worldwide license and the performance of consulting services, which includes the reimbursement of out-of-pocket third-party research and development costs, as its only two performance obligations at inception. The Company further determined that the transaction price, at inception, under the agreement was $10.0 million upfront payment plus the fair value of the Development Costs (as defined in the AZSTARYS License Agreement) which was allocated among the performance obligations based on their respective related stand-alone selling price.

The consideration allocated to the grant of the exclusive, worldwide license was $10.0 million, which reflects the standalone selling price. The Company utilized the adjusted market assessment approach to determine this standalone selling price which included analyzing prospective offers received from various entities throughout our licensing negotiation process as well as the consideration paid to other competitors in the market for a similar type of transaction. The Company determined that the intellectual property licensed under the AZSTARYS License Agreement represented functional intellectual property and it has significant standalone functionality and therefore should be recognized at a point in time as opposed to over time. The revenue related to the grant of the exclusive, worldwide license was recognized at a point in time at the inception of the AZSTARYS License Agreement.

Under the AZSTARYS License Agreement, Commave was granted an exclusive right to first negotiation whereby upon completion of a Phase 1 proof-of-concept study, the Company and Commave may negotiate the economic terms under which certain Additional Products may be included as a Product (both as defined in the AZSTARYS License Agreement) under the AZSTARYS License Agreement (the "Additional Product Option"). In addition to the Additional Product Option, Commave was also granted a ROFR to acquire, license and/or commercialize any of the Additional Product Candidates should they choose not to exercise the Additional Product Option. Should Commave choose to exercise the Additional Product Option on any Additional Product Candidates, Commave and the Company shall negotiate in good faith regarding the economic terms of such Additional Product Candidate. Further, should Commave exercise the ROFR on any Additional Product Candidate, the economic terms of the agreement shall be the same as those offered to the third-party. Under ASC 606 an option to acquire additional goods or services gives rise to a performance obligation if the option provides a material right to the customer. The Company concluded that the above-described Additional Product Option and ROFR do not constitute material rights to the customer as Commave would acquire the goods or services at a to be negotiated price, which the Company expects to approximate fair value and therefore Commave would not receive a material discount on these goods or services compared to market rates.

The Company is entitled to additional payments from Commave conditioned upon the achievement of specified regulatory milestones related to AZSTARYS and KP484 and the achievement of certain U.S. sales milestones. Further, Commave will pay the Company quarterly, tiered royalty payments ranging from a percentage in the high single digits to mid-twenties of Net Sales (as defined in the AZSTARYS License Agreement) in the United States and a percentage in the low to mid-single digits of Net Sales in each country outside of the U.S., in each case subject to specified reductions under certain conditions as described in the AZSTARYS License Agreement. The Company concluded that these regulatory milestones, sales milestones and royalty payments each contain a significant uncertainty associated with a future event. As such, these milestone and royalty payments are constrained at contract inception and are not included in the transaction price as the Company could not conclude that it is probable a significant reversal in the amount of cumulative revenue recognized will not occur surrounding these milestone payments. At the end of each reporting period, the Company updates its assessment of whether the milestone and royalty payments are constrained by considering both the likelihood and magnitude of the potential revenue reversal.

Per the AZSTARYS Amendment, the Company earned a regulatory milestone payment of $10.0 million following the FDA's approval of the AZSTARYS NDA, in March 2021, as well as $10.0 million following the DEA's scheduling of SDX in May 2021. Since the FDA approved the NDA for AZSTARYS and the DEA scheduled SDX, the constraints were removed and revenue recognized. The associated revenue was allocated among the two performance obligations identified at contract inception. Since both performance obligations were satisfied as of the end of each respective quarter of 2021, the full $10.0 million for each milestone was recognized as revenue in the statements of operations for the first quarter and second quarter of 2021, respectively. In accordance with ASC 340-40, *Contracts with Customers*, the Company recognized $1.0 million, respectively, of royalty costs due to payment to Aquestive related to the regulatory milestones earned and recorded it in the item titled royalty and direct contract acquisition costs in the unaudited condensed statements of operations for first and second quarter of 2021.

For the three months ended September 30, 2022, the Company recognized $0.2 million of revenue under the AZSTARYS License Agreement. For the three months ended September 30, 2021, the Company recognized minimal revenue under the AZSTARYS License Agreement. For the nine months ended September 30, 2022, and 2021, the Company recognized revenue under the AZSTARYS License Agreement of $0.4 million and $20.0 million, respectively. There was no deferred revenue related to this agreement as of September 30, 2022, or December 31, 2021.

Consulting Arrangements

The Company enters into consulting arrangements with third parties that fall under the scope of ASC 606. These arrangements may require the Company to deliver various rights, services, including research and development services, regulatory services and/or commercialization support services. The underlying terms of these arrangements generally provide for consideration to the Company in the form of consulting fees and reimbursements of out-of-pocket third-party research and development, regulatory and commercial costs.

Corium Consulting Agreement

In July 2020, the Company entered into a consultation services arrangement (the "Corium Consulting Agreement") with Corium, Inc. ("Corium") under which Corium engaged the Company to guide the product development and regulatory activities for certain current and potential future products in Corium's portfolio, as well as continue supporting preparation for the potential commercial launch of AZSTARYS (together, "Corium Consulting Services"). Corium is a portfolio company of Gurnet Point Capital and was tasked by Commave to lead all commercialization activities for AZSTARYS under the AZSTARYS License Agreement, as discussed above.

Under the Corium Consulting Agreement, the Company was entitled to receive payments from Corium of up to $15.6 million, $13.6 million of which was earned in monthly installments through March 31, 2022, and paid in arrears. The remaining $2.0 million was conditioned upon the approval by the FDA of the NDA for Corium's product candidate, ADLARITY, which was approved by the FDA in the first quarter of 2022. Corium also agreed to be responsible for and reimburse the Company for all development, commercialization and regulatory expenses incurred as part of the performance of the Corium Consulting Services.

The Corium Consulting Agreement is within the scope of ASC 606, as the transaction represents a contract with a customer where the participants function in a customer / vendor relationship and are not exposed equally to the risks and rewards of the activities contemplated under the Corium Consulting Agreement. Using the concepts of ASC 606, the Company identified the performance of consulting services, which includes the reimbursement to the Company of third-party pass-through costs, as its only performance obligation at inception. The Company further determined that the transaction price, at inception, under the agreement was $13.6 million which is the fair value of the consulting services, including the reimbursement of third-party pass-through costs. The Company concluded that the regulatory milestone contains a significant uncertainty associated with a future event. As such, this milestone is constrained at contract inception and is not included in the transaction price as the Company could not conclude that it is probable a significant reversal in the amount of cumulative revenue recognized will not occur surrounding these milestone payments. At the end of each reporting period, the Company updates its assessment of whether the milestone is constrained by considering both the likelihood and magnitude of the potential revenue reversal.

The Company determined that the performance of consulting services, including reimbursement of third-party pass-through costs, is a performance obligation that is satisfied over time as the services are performed and the reimbursable costs are paid. As such, the revenue related to the performance obligation will be recognized as the consulting services are performed and the services associated with the reimbursable third-party pass-through costs are incurred and paid by the Company, in accordance with the practical expedient allowed under ASC 606 regarding an entity's right to consideration from a customer in an amount that corresponds directly to the value to the customer of the entity's performance completed to date. As of March 31, 2022, the Company had recognized approximately all of the consulting services and third-party pass-through costs under the Corium Consulting Agreement.

For the three months ended September 30, 2022, the Company recognized no revenue under the Corium Consulting Agreement related to ADLARITY. For the three months ended September 30, 2021, the Company recognized revenue under the Corium Consulting Agreement related to ADLARITY of $2.0 million. For the nine months ended September 30, 2022, and 2021 the Company recognized revenue under the Corium Consulting Agreement related to ADLARITY of $3.5 million and $5.9 million, respectively. As of September 30, 2022, the Company had no deferred revenue related to this agreement. As of December 31, 2021, the Company had deferred revenue related to this agreement of $0.4 million.

Other Consulting Arrangements

For the three months ended September 30, 2022, the Company recognized revenue under other consulting arrangements of $0.3 million. For the three months ended September 30, 2021, the Company recognized no revenue under other consulting arrangements. For the nine months ended September 30, 2022, and 2021, the Company recognized revenue under other consulting arrangements of $0.6 million and $0.2 million, respectively. There was no deferred revenue from other consulting arrangements as of September 30, 2022, or December 31, 2021.

Arimoclomol Early Access Program

The Company recognizes revenue when fulfilling its performance obligation under the Arimoclomol Early Access Program ("Arimoclomol EAP") by transferring control of promised goods or services to its customer, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. Revenue is recognized net of sales deductions, including discounts, rebates, applicable distributor fees, and revenue-based taxes. The Company recognizes revenue in accordance with ASC 606 and, as a result, follows the five-step model when recognizing revenue: 1) identifying a contract; 2) identifying the performance obligations; 3) determining the transaction price; 4) allocating the price to the performance obligations; and 5) recognizing revenue when the performance obligations have been fulfilled.

Net revenue includes revenue from the sale of arimoclomol for the treatment of Niemann-Pick disease type C ("NPC") under the remunerated early access compassionate use program (“nATU”) in France. An early access compassionate use program is a program giving specific patients access to a drug, which is not yet approved for commercial sale.

Only drugs targeting serious or rare indications and for which there is currently no appropriate treatment are considered for early access compassionate use programs. Further, to be considered for the early access compassionate use program, the drug must have proven efficacy and safety and must either be undergoing price negotiations or seeking marketing approval.

Revenue is recognized when the drug products are sold to the customer, i.e., at the time when control over the drug product is transferred to the third-party customer. Under the French nATU, the manufacturer can set its own price for the drug products until a price agreement with the authorities is in place. Any excess in the price charged by the manufacturer compared to the price agreed with the health authorities once the drug product is approved in France must be repaid. The repayment is considered in the clawback liability.

An estimate of net revenue and clawback liability are recognized using the ‘expected value’ method.

Accounting for net revenue and clawback liability requires determination of the most appropriate method for the expected final transaction price, which depends on the terms and conditions in the contracts with the French Health Authorities and is subject to price negotiations with the French Health Authorities, following a market approval. This estimate also requires assumptions with respect to inputs into the method, including current pricing of comparable marketed products within the rare disease area in France. Management has considered the expected final sales price as well as the price of similar drug products.

Management has based their initial sales prices on comparable drug products for arimoclomol and the estimate of the clawback liability on the basis of the average cost of treatment which the authorities are expected to cover.

Management’s assumptions are based on available relevant market information regarding average treatment cost of the most comparable drugs possible in the rare disease area in Europe. The Company is operating within a rare disease therapeutic area where there is unmet treatment need and hence a limited number of comparable commercialized drugs products. The limited available relevant market information for directly comparable commercialized drugs within rare disease increases the uncertainty in management's estimate.

The Company records revenues from product sales when there is a transfer of control of the product from the Company to the customer. The Company typically determines transfer of control based on when the product is shipped or delivered and title passes to the customer. In determining when the customer obtains control of the product, the Company considers certain indicators, including whether the Company has a present right to payment from the customer, whether title and/or significant risks and rewards of ownership have transferred to the customer and whether customer acceptance has been received. For the three months ended September 30, 2022, the Company recognized revenue related to the Arimoclomol EAP in France of $2.3 million, which is net of a clawback liability of $1.2 million. For the nine months ended September 30, 2022, the Company recognized revenue related to the Arimoclomol EAP in France of $3.2 million, which is net of a clawback liability of $1.7 million.

As part of the Arimoclomol Purchase Agreement the Company assumed an estimated reserve liability of $5.2 million related to revenue generated from the Arimoclomol EAP in France. The total estimate reserve liability as of September 30, 2022, including the additional clawback liability for the three and nine months ended September 30, 2022, was $6.3 million. As of September 30, 2022, this estimated reserve liability is recorded as discount and rebate liabilities in the unaudited condensed consolidated balance sheet and is separated into current and long-term based upon the timing of the expected payment to the French regulators.

Accounts and Other Receivables

Accounts and other receivables consist of receivables under the AZSTARYS License Agreement and Arimoclomol EAP, as well as receivables related to consulting arrangements, income tax receivables and other receivables due to the Company. Receivables under the AZSTARYS License Agreement are recorded for amounts due to the Company related to reimbursable third-party costs and royalties on product sales. Receivables under the Arimoclomol EAP are recorded for product sales under the program in France. These receivables, as well as the receivables related to consulting arrangements, are evaluated to determine if any reserve or allowance should be established at each reporting date. As of September 30, 2022, the Company had receivables related to the Arimoclomol EAP of $4.9 million, consulting arrangements of $0.6 million, income tax receivables of $0.7 million and other receivables of $0.4 million. As of December 31, 2021, the Company had receivables related to the Corium Consulting Agreement of $1.2 million, AZSTARYS License Agreement of $0.1 million, income tax receivables of $0.1 million and other consulting arrangements of $0.1 million. As of September 30, 2022, and December 31, 2021, no reserve or allowance for doubtful accounts has been established.

Application of New or Revised Accounting Standards—Adopted

From time to time, the Financial Accounting Standards Board (the "FASB") or other standard-setting bodies issue accounting standards that are adopted by the Company as of the specified effective date.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40); Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), which addresses issues identified as a result of the complexities associated with applying U.S. GAAP for certain financial instruments with characteristics of liabilities and equity. This update addresses, among other things, the number of accounting models for convertible debt instruments and convertible preferred stock, targeted improvements to the disclosures for convertible instruments and earnings-per-share ("EPS") guidance and amendments to the guidance for the derivatives scope exception for contracts in an entity's own equity, as well as the related EPS guidance. This update applies to all entities that issue convertible instruments and/or contracts in an entity's own equity. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years. FASB specified that an entity should adopt the guidance as of the beginning of its annual fiscal year. The adoption of ASU 2020-06 did not have a material impact on the Company's unaudited condensed financial statements and disclosures.

In May 2021, the FASB issued 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, a consensus of the FASB Emerging Issues Task Force* ("ASU 2021-04"), which aims to clarify and reduce diversity in issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. This update applies to all entities that issue freestanding written call options that are classified in equity. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years. FASB specified that an entity should adopt the guidance as of the beginning of its annual fiscal year. The adoption of ASU 2021-04 did not have a material impact on the Company's unaudited condensed financial statements and disclosures.

C. Debt Obligations

As of September 30, 2022, and December 31, 2021, the Company had no convertible notes outstanding.

Deerfield Facility Agreement

In June 2014, the Company entered into a $60 million multi-tranche credit facility (the "Deerfield Facility Agreement") with Deerfield Private Design Fund III, LP ("Deerfield"). At the time the Company entered into the Deerfield Facility Agreement, the Company borrowed the first tranche, which consisted of a term loan of $15 million (the "Term Note") and a senior secured loan of $10 million (the "Deerfield Convertible Note"). Deerfield was able to convert any portion of the outstanding principal and any accrued but unpaid interest on the Deerfield Convertible Note into shares of the Company's common stock at an initial conversion price of $5.85 per share (the "Deerfield Note Put Option"). After giving effect to the Reverse Stock Split effected in December 2020, the conversion price became $93.60.

The Deerfield Convertible Note originally bore interest at 9.75% per annum but was subsequently reduced to 6.75%. Interest accrued on the outstanding balance under the Deerfield Convertible Note was due quarterly in arrears. The Company originally had to repay one-third of the outstanding principal amount of the Deerfield Convertible Note on the fourth and fifth anniversaries of the Deerfield Facility Agreement (June 2018 and June 2019). In June 2018, Deerfield agreed to convert approximately $3.3 million of the principal amount then due, plus approximately $0.2 million of accrued interest, into 37,410 shares of our common stock (as discussed below in the section entitled "Facility Agreement Waiver and Fifth Amendment to Senior Secured Convertible Note"). In September 2019, the Company entered into an amendment with Deerfield in order to (i) reduce the interest rate applicable under the Deerfield Facility Agreement from 9.75% to 6.75%, (ii) provide for "payment in kind" of interest on the Loans (as defined in the Deerfield Facility Agreement), and (iii) defer the Loan payments due pursuant to the Deerfield Facility Agreement until June 1, 2020 (as discussed below in the section entitled "2021 Note Exchange Effected in September 2019"). In December 2019, the Company entered into another amendment with Deerfield in order to (i) defer the Loan payments due pursuant to the Deerfield Facility Agreement until March 31, 2021, and (ii) allow for the entries of additional debt and debt holders under the Deerfield Facility Agreement (as discussed below in the section entitled "2021 Note Exchange Effected in December 2019"). The Company was also obligated to repay principal of the Deerfield Convertible Note in the amount of approximately $7.0 million plus any capitalized interest to date on March 31, 2021. Prepayment of the outstanding balance was not allowed without written consent of Deerfield.

Pursuant to the Deerfield Facility Agreement, the Company issued to Deerfield a warrant to purchase 14,423,076 shares of Series D Preferred at an initial exercise price of $0.78 per share, which is exercisable until June 2, 2024 (the "Deerfield Warrant"). Upon completion of the Company's initial public offering, the Deerfield Warrant automatically converted into a warrant to purchase 1,923,077 shares of the Company's common stock at an exercise price of $5.85 per share. After giving effect to the Reverse Stock Split effected in December 2020, the shares issuable upon conversion of the warrant became 120,192 shares of common stock, and the exercise price of the Deerfield Warrant became $93.60 per share, which in January 2021 and June 2021 was further adjusted to $46.25 and $38.34 per share, respectively, in connection with the Company entering into the January 2021 and June 2021 Inducement Transactions (as defined in Note F) each of which triggered the anti-dilution provisions of the Deerfield Warrant. This warrant qualifies as a participating security under ASC Topic 260, Earnings per Share, and is treated as such in the net loss per share calculation (Note I). If a Major Transaction occurs (as defined in the Deerfield Facility Agreement) Deerfield may require the Company to redeem the Deerfield Warrant for a cash amount equal to the Black-Scholes value of the portion of the Deerfield Warrant to be redeemed (the "Warrant Put Option").

The Company recorded the fair value of the shares of Series D Preferred to debt issuance costs on the date of issuance. The Company also recorded the fair value of the Deerfield Warrant and the embedded Warrant Put Option to debt discount on the date of issuance. The debt issuance costs and debt discount were amortized over the term of the related debt and the expense was recorded as interest expense related to amortization of debt issuance costs and discount in the statements of operations. In the first quarter of 2021, the debt was extinguished, through a series of debt payments and a conversion of debt principal and interest to Series B-2 Preferred Stock. As a result of the debt extinguishment, the associated discount and debt issuance costs were written off and recorded as a loss on extinguishment.

Pursuant to the Deerfield Facility Agreement, the Company was not able to enter into specified transactions, including a debt financing in the aggregate value of $750,000 or more, other than permitted indebtedness under the Deerfield Facility Agreement, a merger, an asset sale or any other change of control transaction or any joint venture, partnership or other profit-sharing arrangement, without the prior approval of the Required Lenders (as defined in the Deerfield Facility Agreement). Additionally, if the Company were to enter into a major transaction, including a merger, consolidation, sale of substantially all of its assets or other change of control transaction, Deerfield would have had the ability to demand that prior to consummation of such transaction the Company repay all outstanding principal and accrued interest of any notes issued under the Deerfield Facility Agreement. Under each warrant issued pursuant to the Deerfield Facility Agreement, Deerfield has the right to demand that the Company redeem the warrant for a cash amount equal to the Black-Scholes value of a portion of the warrant upon the occurrence of specified events, including a merger, an asset sale or any other change of control transaction.

Issuance of* 5.50% *Senior Convertible Notes and Third Amendment to Senior Secured Convertible Note and Warrant

In February 2016, the Company issued $86.3 million aggregate principal amount of its 5.50% Senior Convertible Notes due 2021 (the "2021 Notes") to Cowen and RBC Capital Markets, LLC, as representatives of the several initial purchasers (the "Initial Purchasers"), who subsequently resold the 2021 Notes to qualified institutional buyers (the "Note Offering") in reliance on the exemption from registration provided by Rule 144A under the Securities Act of 1933, as amended (the "Securities Act").

The 2021 Notes were issued pursuant to an indenture, dated as of February 9, 2016 (the "Indenture"), between the Company and U.S. Bank National Association, as trustee (the "Trustee"). Interest on the 2021 Notes was payable semi-annually in cash in arrears on February 1 and August 1 of each year, beginning on August 1, 2016, at a rate of 5.50% per year. The 2021 Notes had an original maturity of February 1, 2021 unless earlier converted or repurchased.

The net proceeds from the Note Offering were approximately $82.8 million, after deducting the Initial Purchasers' discount and estimated offering expenses. Concurrent with the Note Offering, the Company used approximately $18.6 million of the net proceeds from the Note Offering to repay in full the Term Note, plus all accrued but unpaid interest, a make-whole interest payment and a prepayment premium on the Term Note.

The 2021 Notes were not redeemable prior to the maturity date, and no sinking fund was provided for the 2021 Notes. The 2021 Notes were convertible at an initial conversion rate of 58.4454 shares of the Company's common stock per $1,000 principal amount of the 2021 Notes, subject to adjustment under the Indenture, which is equal to an initial conversion price of approximately $17.11 per share of common stock. After giving effect to the Reverse Stock Split effected in December 2020, the conversion rate of the 2021 Notes would have been approximately 3.6528 shares of the Company's common stock per $1,000 principal amount of the 2021 Notes, which is equal to a conversion price of approximately $273.76 per share.

If the Company underwent a "fundamental change" (as defined in the Indenture), holders could have required that the Company repurchase for cash all or any portion of their 2021 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2021 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The Indenture included customary terms and covenants, including certain events of default after which the 2021 Notes may have become due and payable immediately.

As described in more detail below, in multiple exchanges occurring in December 2019 and January 2020, all outstanding 2021 Notes were exchanged by the holders thereof for either shares of our common stock or senior secured convertible promissory notes issued under the terms of the Deerfield Facility Agreement.

2021 Note Exchange Effected in December 2019

In December 2019, the Company entered into the December 2019 Exchange Agreement and Amendment to Facility Agreement, Senior Secured Convertible Notes and Warrants (the "December 2019 Exchange Agreement") with the Deerfield Lenders and Delaware Street Capital Master Fund, L.P. ("DSC" and, collectively with the Deerfield Lenders, the "December 2019 Holders"). Under the December 2019 Exchange Agreement, the Company issued senior secured convertible promissory notes under the Deerfield Facility Agreement in the aggregate principal amount of approximately $71.4 million (the "December 2019 Notes"), in exchange for the cancellation of an aggregate of approximately $71.4 million principal amount and accrued interest of the Company's 2021 Notes. Upon entering into the December 2019 Exchange Agreement, the Company agreed to pay the December 2019 Holders, in the aggregate, an interest payment of approximately $0.7 million which represents 50% of the accrued interest, as of December 18, 2019, on the 2021 Notes owned by the December 2019 Holders. The remainder of such interest was included in the principal amount of the December 2019 Notes.

The December 2019 Notes bore interest at 6.75% per annum. The December 2019 Notes were convertible into shares of the Company's common stock at an initial conversion price of $17.11 per share (which represented the conversion price of the 2021 Notes), subject to adjustment in accordance with the terms of the December 2019 Notes. After giving effect to the Reverse Stock Split effected in December 2020, the conversion price of the December 2019 Notes would have been $273.76 per share. The Company subsequently amended the December 2019 Notes to provide that such notes would have been convertible into shares of the Company's common stock at a conversion price of $93.60 per share (which represented the conversion price of the Deerfield Convertible Note). The conversion price of the December 2019 Notes would have been adjusted downward if the Company issued or sold any shares of common stock, convertible securities, warrants or options at a sale or exercise price per share less than the greater of the December 2019 Notes' conversion price or the closing sale price of the Company's common stock on the last trading date immediately prior to such issuance, or, in the case of a firm commitment underwritten offering, on the date of execution of the underwriting agreement between the Company and the underwriters for such offering. However, if the Company effected an "at the market offering" as defined in Rule 415 of the Securities Act, of its common stock, the conversion price of the December 2019 Notes would have been adjusted downward pursuant to this anti-dilution adjustment only if such sales were made at a price less than $93.60 per share, provided that this anti-dilution adjustment would not have applied to any sales made under (x) the 2020 ELOC Agreement, (y) the ATM Agreement, or (z) the September 2019 Exchange Agreement (as amended). Notwithstanding anything to the contrary in the December 2019 Notes, the anti-dilution adjustment of such notes would not have resulted in the conversion price of the December 2019 Notes being less than $9.328 per share. The December 2019 Notes were convertible at any time at the option of the holders thereof, provided that a holder of a December 2019 Note was prohibited from converting such note into shares of the Company's common stock if, as a result of such conversion, such holder (together with certain affiliates and "group" members) would have beneficially owned more than 4.985% of the total number of shares of common stock then issued and outstanding. However, the December 2019 Note issued to DSC, due to the fact DSC was a beneficial owner of more than 4.985% of the total number of shares of the Company's common stock then issued and outstanding, had a beneficial ownership cap equal to 19.985% of the total number of shares of the Company's common stock then issued and outstanding. Pursuant to the December 2019 Notes, the December 2019 Holders had the option to demand repayment of all outstanding principal, and any unpaid interest accrued thereon, in connection with a Major Transaction (as defined in the December 2019 Notes), which included, among others, any acquisition or other change of control of the Company; a liquidation, bankruptcy or other dissolution of the Company; or if at any time after March 31, 2021, shares of the Company's common stock are not listed on an Eligible Market (as defined in the December 2019 Notes). The December 2019 Notes were subject to specified events of default, the occurrence of which would have entitled the December 2019 Holders to immediately demand repayment of all outstanding principal and accrued interest on the December 2019 Notes. Such events of default included, among others, failure to make any payment under the December 2019 Notes when due, failure to observe or perform any covenant under the Deerfield Facility Agreement (as defined below) or the other transaction documents related thereto (subject to a standard cure period), the failure of the Company to be able to pay debts as they come due, the commencement of bankruptcy or insolvency proceedings against the Company, a material judgement levied against the Company and a material default by the Company under the Deerfield Warrant, the December 2019 Notes or the Deerfield Convertible Note.

The December 2019 Exchange Agreement amended the Deerfield Facility Agreement in order to, among other things, (i) provide for the Deerfield Facility Agreement to govern the December 2019 Notes received by the December 2019 Holders pursuant to the December 2019 Exchange Agreement, (ii) extend the maturity of the Deerfield Convertible Note from February 14, 2020 and June 1, 2020, as applicable, to March 31, 2021, (iii) defer interest payments on the Deerfield Convertible Note until March 31, 2021 (which such interest shall accrue as "payment-in-kind" interest), (iv) designate DSC as a Lender under (and as defined in the Deerfield Facility Agreement), (v) name Deerfield as the "Collateral Agent" for all Lenders and (vi) modify the terms and conditions under which the Company may issue additional pari passu and subordinated indebtedness under the Deerfield Facility Agreement (subject to certain conditions specified in the Deerfield Facility Agreement).

The December 2019 Exchange Agreement also amended and restated the Deerfield Convertible Note to conform the definitions of "Eligible Market" and "Major Transactions" to the definition in the December 2019 Notes, to remove provisions that were only applicable prior to the Company's initial public offering and to make certain other changes to conform to the December 2019 Notes. The conversion price for the Deerfield Convertible Note remained $93.60 per share, subject to adjustment on the same basis as the December 2019 Notes.

The December 2019 Exchange Agreement also amended the Deerfield Warrant to conform the definitions of "Eligible Market" and "Major Transaction" in the Deerfield Warrant with the definitions of such terms in the December 2019 Notes.

The December 2019 Exchange Agreement contained customary representations, warranties and covenants made by the Company and the December 2019 Holders, including a covenant of the Company to, upon request, use commercially reasonable efforts to use its technology to discover a product based upon a compound that may be identified by the Deerfield Lenders in a manner that is reasonably acceptable to the Deerfield Lenders, or one of their affiliates, with the terms of such discovery plan, including the Company's compensation thereunder, to be mutually agreed to by the parties.

In connection with entering into the December 2019 Exchange Agreement, on December 18, 2019, the Company amended and restated that certain Guaranty and Security Agreement, dated June 2, 2014, by and between the Company and the other parties thereto (the "GSA") to, among other things, (i) provide that all of the notes will be secured by the liens securing the indebtedness under the Deerfield Facility Agreement, and (ii) name Deerfield as the "Collateral Agent" under the GSA.

In connection with entering into the December 2019 Exchange Agreement, the Company also entered into an amendment (the "September 2019 Exchange Agreement Amendment") to the September 2019 Exchange Agreement to, among other things, (i) amend and restate Annex I of the September 2019 Exchange Agreement to allow the Deerfield Lenders to effect optional exchanges of the December 2019 Notes and the Deerfield Convertible Note under the terms of the September 2019 Exchange Agreement; (ii) amend the common stock exchange price under the September 2019 Exchange Agreement to be a per share price equal to the greater of (x) $0.60, subject to adjustment to reflect stock splits and similar events, or (y) the average of the volume-weighted average prices of the Company's common stock on each of the 15 trading days immediately preceding such exchange, (iii) provide that no more than 28,439,015 of shares of the Company's common stock shall be issued pursuant to optional exchanges under the September 2019 Exchange Agreement (whether by common stock exchange or upon conversion of Series B-2 Shares (as defined in the September 2019 Exchange Agreement Amendment)), subject to adjustment to reflect stock splits and similar events and (iv) eliminate limitations regarding the timing and aggregate amount of principal which may be exchanged under the September 2019 Exchange Agreement. These changes in the September 2019 Exchange Agreement Amendment significantly modified the Optional Exchange Principal Amount, as such after giving effect to the September Exchange Agreement Amendment the Optional Exchange Principal Amount ceases to exist the new optional exchanges are referred to as the Deerfield Optional Conversion Feature. After giving effect to the Reverse Stock Split effected in December 2020, the exchange price of the Deerfield Optional Conversion Feature would have been $9.60 per share or the average of the volume-weighted average price of the common stock on the principal securities exchange or trading market on which the common stock is then trading on each of the 15 trading days immediately preceding such exchange and the shares of the Company's common stock issued pursuant to the optional exchanges would have been 1,777,437 shares of common stock.

In connection with entering into the September 2019 Amendment, the Company filed an amendment to the Series B-2 Certificate of Designation (the "Series B-2 Certificate of Designation Amendment") with the Secretary of State of the State Delaware. The Series B-2 Certificate of Designation Amendment provides that each share of the Company's Series B-2 preferred stock is convertible into shares of the Company's common stock at a per share price equal to the common stock exchange price under the September 2019 Exchange Agreement, which equals the greater of (i) $9.60 (subject to adjustment to reflect stock splits and similar events), or (ii) the average of the volume-weighted average prices of the Company's common stock on each of the 15 trading days immediately preceding such exchange.

As of September 30, 2020, the Deerfield Lenders had converted all $17.1 million of principal under the December 2019 Notes into all 1,777,437 shares of common stock available under the Deerfield Optional Conversion Feature.

The Company determined the changes to the Deerfield Convertible Note met the definition of a troubled debt restructuring under ASC 470-60, Troubled Debt Restructurings by Debtors, as the Company was experiencing financial difficulties and Deerfield granted a concession. The amendments to the terms of the Deerfield Convertible Note resulted in no gain on restructuring because the total cash outflows required under the amended Deerfield Convertible Note exceeded the carrying value of the original Deerfield Convertible Note immediately prior to amendment. Prospectively, the Deerfield Convertible Note will continue to be carried net of the associated discount and debt issuance costs which will be amortized and recorded as interest expense using a modified effective interest rate based on the amendments.

The changes to the 2021 Notes, under the December 2019 Exchange Agreement, referred to after as the December 2019 Notes, were accounted for as a debt modification, prospectively, the December 2019 Notes will be carried net of the associated discount and debt issuance costs which will be amortized and recorded as interest expense using a modified effective interest rate based on the amendments.

2021 Note Exchange Effected in January 2020

In January 2020, the Company entered into the January 2020 Exchange Agreement (the "January 2020 Exchange Agreement") with M. Kingdon Offshore Master Fund, LP ("Kingdon"). Under the January 2020 Exchange Agreement, the Company issued a senior secured convertible note in the aggregate principal amount of approximately $3.0 million (the "January 2020 Note") in exchange for the cancellation of an aggregate of $3.0 million principal amount and accrued interest of the 2021 Note then owned by Kingdon. Upon entering into the January 2020 Exchange Agreement, the Company agreed to pay Kingdon an interest payment of approximately $37,000, which represents 50% of the accrued and unpaid interest, as of January 13, 2020, on Kingdon's 2021 Note. The remainder of such interest was included in the principal amount of the January 2020 Note.

The January 2020 Note was issued with substantially the same terms and conditions as the December 2019 Notes (as amended by the amendment described in more detail below).

In connection with entering into the January 2020 Exchange Agreement, the Company entered into an Amendment to Facility Agreement and December 2019 Notes and Consent (the "December 2019 Note Amendment") with the December 2019 Holders that, among other things, (i) amended the December 2019 Notes to (a) reduce the Conversion Price (as defined in the December 2019 Notes) from $17.11 to $5.85 per share and (b) increased the Floor Price (as defined in the December 2019 Notes) from $0.38 to $0.583 per share, and (ii) amended the Deerfield Facility Agreement to (x) provide for Kingdon to join the Deerfield Facility Agreement as a Lender (as defined in the Deerfield Facility Agreement) and (y) provide that the 2020 Note and shall constitute a "Senior Secured Convertible Note" (as defined in the Deerfield Facility Agreement) for purposes of the Deerfield Facility Agreement and other Transaction Documents (as defined in the Deerfield Facility Agreement). After giving effect to the Reverse Stock Split effected in December 2020, the Conversion Price became $93.60 per share and the Floor Price became $9.328 per share.

The changes to the 2021 Note, under the January 2020 Exchange Agreement, referred to after as the January 2020 Note, were accounted for as a debt modification, prospectively, the January 2020 Note will be carried net of the associated discount and debt issuance costs which will be amortized and recorded as interest expense using a modified effective interest rate based on the amendments.

December 2020 Exchange Agreement and Amendment to Facility Agreement, Notes and Investors' Rights Agreement

In December 2020, the Company entered into a December 2020 Exchange Agreement and Amendment to Facility Agreement, Notes and Investors' Rights Agreement, as amended (the "December 2020 Exchange Agreement") with the Deerfield Lenders, DSC and Kingdon (collectively, the "Facility Agreement Note Holders"). Under the December 2020 Exchange Agreement, the Company and the Facility Agreement Note Holders agreed that (a) the Company will make a cash pre-payment of a portion of principal amount of the Deerfield Convertible Note, the December 2019 Notes and the January 2020 Note (collectively, the "Facility Agreement Notes") to the Facility Agreement Note Holders (the "Debt Payment") equal to approximately $30.3 million, plus accrued interest if such payment is made on or after January 1, 2021, and (b) subject to the satisfaction or waiver of certain conditions specified in the December 2020 Exchange Agreement, including the making of the Debt Payment, issue shares of its Series B-2 Preferred Stock and warrants exercisable for shares of its common stock (the "Exchange Warrants"), in exchange for the cancellation of a portion of the principal amount of the Facility Agreement Notes owned by the Facility Agreement Note Holders in an aggregate amount equal to the Debt Payment, plus the Q4 PIK Interest Payment (as defined in the December 2020 Exchange Agreement) (such transaction, the "December 2020 Exchange").

The December 2020 Exchange Agreement amended the Facility Agreement Notes to provide that the failure of the Company's common stock to remain listed on an eligible securities market will not constitute a "Major Transaction" unless such failure occurs after March 31, 2023.

Subject to the satisfaction or waiver of certain conditions specified in the December 2020 Exchange Agreement, including the making of the Debt Payment and the consummation of the exchange, the December 2020 Exchange Agreement amended that certain Facility Agreement dated as of June 2, 2014, as amended (the "Facility Agreement"), by and among the Company and the Facility Agreement Note Holders in order to, among other things, (i) extend the maturity date of the Facility Agreement Notes to March 31, 2023, (ii) provide for cash payments of interest on the Loans (as defined in the Facility Agreement) for the periods following July 1, 2021, and (iii) provide for specified prepayment terms on the Loans.

The December 2020 Exchange Agreement amended that certain Amended and Restated Investors' Rights Agreement, dated as of February 19, 2015 (the "IRA"), by and among the Company, Deerfield and the other parties signatory thereto in order to, among other things, add Deerfield Special Situations Fund, L.P. as a party thereto and to give effect to the issuance of the Exchange Warrants and the Company's registration obligations under the December 2020 Exchange Agreement (as described in more detail below).

The Exchange Warrants issued pursuant to the December 2020 Exchange Agreement were exercisable for a number of shares of the Company's common stock equal to 75% of the shares of common stock issuable upon conversion of the Series B-2 Preferred Stock issued in the Exchange (without regard for any beneficial ownership limitations included therein). The Exercise Warrants were subject to substantially the same terms and conditions as the warrants issued to the public in the public offering of the Company's securities contemplated pursuant to a registration statement on Form S-1 (File No. 333-250945) (the "Public Offering"), with an exercise price equal to the exercise price per share of the warrants issued in the Public Offering and provided that the Facility Agreement Note Holders will be limited from exercising such Exchange Warrants if, as a result of such exercise, such holders (together with certain affiliates and "group" members of such holders) would beneficially own more than 4.985% of the total number of shares of the Company's common stock then issued and outstanding.

In anticipation of the Public Offering, and to meet the Nasdaq Listing Requirements, the Company agreed in December 2020 to restructure the December 2019 Notes and the January 2020 Note in the aggregate principal amount of $60.8 million and the Deerfield Note in the principal amount of $7.5 million (collectively the "the Facility Notes"). The total outstanding principal and accrued interest under the Facility Notes was $69.4 million as of December 31, 2020.

Under the terms of the December 2020 Exchange Agreement, the Company, on January 12, 2021, in connection with the closing of the Public Offering:

- Exchanged $31.5 million of the outstanding principal and accrued interest on the Facility Notes for (i) 31,476.98412 shares of Series B-2 Preferred Stock, and (ii) Exchange Warrants exercisable for 3,632,019 shares of the Company's common stock, and
- Made a payment of $30.3 million (the "Debt Payment"), in partial repayment of the remaining outstanding principal and accrued interest of the Facility Notes.

Following the completion of these transactions, the aggregate balance of principal and accrued interest remaining outstanding under the Facility Notes was approximately $7.6 million. With respect to this remaining outstanding balance under the Facility Notes, the December 2020 Exchange Agreement amended the terms of that debt to provide that:

- The maturity date was changed to March 31, 2023, and the debt was prepayable upon specified conditions, and
- Interest would accrue at the rate of 6.75% per annum, payable quarterly, would be added to principal until June 30, 2021, and then be payable in cash thereafter.

The changes to the Facility Notes, under the December 2020 Exchange Agreement, were accounted for as a debt extinguishment as the cash flows immediately after the December 2020 Exchange Agreement were substantially different from the cash flows immediately prior to the December 2020 Exchange Agreement and while the Company was experiencing financial difficulties it was determined that the lender did not grant a concession. As such, a loss of extinguishment related to the extinguishment of the old notes was recorded in the unaudited condensed statement of operations for the three months ended March 31, 2021, and additional debt issuance costs related the new notes were capitalized and amortized using the effective interest method through the Payoff of Facility Agreement Notes (discussed below).

The transactions contemplated under the December 2020 Exchange Agreement, including the obligation to pre-pay any portion of the Facility Agreement Notes or to complete the Exchange and the effectiveness of the amendments to the Facility Agreement, the Notes and the IRA, were subject to specified conditions of closing, including certain closing of the Public Offering, the filing of the Restated Series B-2 Certificate of Designation (as defined below) and the approval for listing of the Company's common stock, including the shares issuable upon conversion of the Series B-2 Preferred Stock and exercise of the Exchange Warrants, on the Nasdaq Capital Market.

As a condition to closing of the December 2020 Exchange Agreement, the Company filed an Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Convertible Preferred Stock (the "Restated Series B-2 Certificate of Designation") with the Secretary of State of the State Delaware, setting forth the preferences, rights and limitations of the Series B-2 Preferred Stock.

Each share of Series B-2 Preferred Stock had an aggregate stated value of $1,000 and was convertible into shares of the Company's common stock at a per share price equal to the price per share to the public of the Company's common stock in the Public Offering (subject to adjustment to reflect stock splits and similar events).

The Series B-2 Preferred Stock was convertible at any time on or after the PDUFA Date (as defined in the Restated Series B-2 Certificate of Designation) at the option of the holders thereof; provided that the holders thereof will be prohibited from converting shares of Series B-2 Preferred Stock into shares of the Company's common stock if, as a result of such conversion, such holders (together with certain affiliates and "group" members of such Holders) would beneficially own more than 4.985% of the total number of shares of the Company's common stock then issued and outstanding. The Series B-2 Preferred Stock is not redeemable. In the event of the Company's liquidation, dissolution or winding up or a change in control of the Company (each, a "Liquidation Event"), the holders of Series B-2 Preferred Stock will receive, prior to any distribution or payment on our common stock, an amount equal to the greater of (i) $1,000 per share (in the case of a change in control, transaction consideration with such value), or (ii) the amount (in the case of a change in control, in the form of the transaction consideration) per share each such holder would have been entitled to receive if every share of Series B-2 Preferred Stock had been converted into common stock immediately prior to such Liquidation Event, in each case, plus any declared but unpaid dividends thereon. With respect to rights upon liquidation, the Series B-2 Preferred Stock ranks senior to the common stock, on parity with any Parity Securities (as defined in the Restated Series B-2 Certificate of Designation) and junior to existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions involving the Company's organizational documents that adversely affect the holders of Series B-2 Preferred Stock and other specified matters regarding the rights, preferences and privileges of the Series B-2 Preferred Stock), the Series B-2 Preferred Stock did not have voting rights. The Series B-2 Preferred Stock is not subject to any price-based anti-dilution protections and does not provide for any accruing dividends but provides that holders of Series B-2 Preferred Stock will participate in any dividends on the Company's common stock on an as-converted basis (without giving effect to the limitation on conversion described above). The Restated Series B-2 Certificate of Designation also provides for partial liquidated damages in the event that the Company fails to timely convert shares of Series B-2 Preferred Stock into common stock in accordance with the Restated Series B-2 Certificate of Designation.

Payoff of Facility Agreement Notes and Termination of Facility Agreement

On February 8, 2021, the Company entered into a payoff letter with the Facility Agreement Note Holders, pursuant to which the Company agreed to pay off and thereby terminate the Facility Agreement.

Pursuant to the payoff letter, the Company paid a total of $8.0 million to the Facility Agreement Note Holders, representing the principal balance, accrued interest outstanding and a prepayment fee in repayment of the Company's outstanding obligations under the Facility Agreement.

Pursuant to the payoff letter, all outstanding indebtedness and obligations of the Company owing to the Facility Agreement Note Holders under the Facility Agreement have been paid in full. The Facility Agreement and the notes thereunder, as well as the security interests in the assets of the Company securing the Facility Agreement and note obligations, have been terminated. The Facility Agreement Note Holders will retain the warrants previously issued to them by the Company.

The Company determined the payoff letter met the liability derecognition threshold under ASC 405-20, *Liabilities - Extinguishment of Liabilities*, as the Company repaid the debt (and has been relieved of the related obligation) without entering into new debt with the Facility Agreement Note Holders and there is no other continuing debt with the Facility Agreement Note Holders. The payoff letter resulted in a loss on extinguishment of debt which was shown within other (expense) income in the unaudited condensed statements of operations for the three months ended March 31, 2021.

PPP Loan

On April 23, 2020, the Company received proceeds of $0.8 million from the PPP Loan under the PPP of the CARES Act, a portion of which may be forgiven, which the Company used to retain current employees, maintain payroll and make lease and utility payments. In May 2021, the Company received notice from the U.S. Small Business Administration that the principal and interest due under its PPP Loan had been forgiven in full.

Line of Credit

On May 31, 2022, the Company and Ameris Bank, as lender, entered into a $20.0 million revolving loan agreement (the "Line of Credit"). Proceeds of the revolving facility provided by the Line of Credit are to be used for general corporate purposes. Loans under the Line of Credit bear interest at the Secured Overnight Financing Rate ("SOFR") plus 1.60%, with a SOFR floor of 0.00%.

The revolving facility under the Line of Credit is secured by a perfected security interest in deposit accounts. The revolving facility under the Line of Credit is subject to customary affirmative and negative covenants.

The latest maturity date of the loans under the Line of Credit is May 31, 2025. The Line of Credit contains customary events of default that could lead to an acceleration of the loans, including cross-default, bankruptcy and payment defaults. As of September 30, 2022, the Company has drawn $12.8 million from the Line of Credit to finance the transactions under the Arimoclomol Purchase Agreement, and this amount is supported by a $12.8 million certificate of deposit which is shown as long-term investments in the unaudited condensed consolidated balance sheets. The remaining $7.2 million under the Line of Credit is in a separate interest-bearing certificate of deposit and is also recorded as long-term investments in the unaudited condensed consolidated balance sheet as of September 30, 2022. These certificates of deposit are pledged as collateral against the Line of Credit and cannot be redeemed so long as the $20.0 million remains available under the Line of Credit. The total value of the certificates of deposit held with Ameris Banks must meet or exceed the amount available to borrow under the Line of Credit so long as the Line of Credit remains active.

D. Commitments and Contingencies

From time to time, the Company is involved in various legal proceedings arising in the normal course of business. For some matters, a liability is not probable, or the amount cannot be reasonably estimated and, therefore, an accrual has not been made. However, for such matters when it is probable that the Company has incurred a liability and can reasonably estimate the amount, the Company accrues and discloses such estimates. As of September 30, 2022, and December 31, 2021, no accruals have been made related to commitments and contingencies.

E. Preferred Stock and Warrants

Authorized, Issued, and Outstanding Preferred Stock

As of September 30, 2022, and December 31, 2021, the Company had 10,000,000 shares of authorized, unallocated and unissued preferred stock.

In June 2021, the Company filed with the Secretary of State of the State of Delaware: (i) a Certificate of Elimination of Series A Convertible Preferred Stock, eliminating from the Company's Certificate of Incorporation the 9,578 shares designated as Series A Convertible Preferred Stock; (ii) a Certificate of Elimination of Series B-1 Convertible Preferred Stock, eliminating from the Company's Certificate of Incorporation the 1,576 shares designated as Series B-1 Convertible Preferred Stock; and (iii) a Certificate of Elimination of Series B-2 Convertible Preferred Stock, eliminating from the Company's Certificate of Incorporation the 31,480 shares designated as Series B-2 Convertible Preferred Stock. As of September 30, 2022, and December 31, 2021, no shares of preferred stock were designated, issued or outstanding.

Series B-2 Preferred Stock

Pursuant to the December 2020 Exchange Agreement, on January 12, 2021, the Company issued to the Facility Note Holders an aggregate of 31,476.98412 shares of its Series B-2 Preferred Stock and warrants exercisable for an aggregate of 3,632,019 shares of the Company's common stock (the "Exchange Warrants").

The Series B-2 Preferred Stock was convertible into an aggregate of 4,842,690 shares of the Company's common stock upon issuance at a conversion price equal to $6.4999. No fractional shares of common stock will be issued in connection with the conversion of the Series B-2 Preferred Stock. Instead, for any such fractional share that would have otherwise been issued upon conversion of a share of Series B-2 Preferred Stock, the Company will round such fraction up to the next whole share.

Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of the Series B-2 Convertible Preferred Stock

On January 11, 2021, as a condition to closing of the transactions contemplated by the December 2020 Exchange Agreement, the Company filed an Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Convertible Preferred Stock (the "Series B-2 Certificate of Designation") with the Secretary of State of the State Delaware, setting forth the preferences, rights and limitations of the Series B-2 Preferred Stock.

Immediately following, the closing of the Public Offering, pursuant to the terms of the December 2020 Exchange Agreement, the Company:

- Exchanged approximately $31.5 million (the "Exchange") of the outstanding principal and accrued interest on the Facility Notes for (i) the Series B-2 Preferred Stock and (ii) the Exchange Warrants; and

- made a payment of approximately $30.3 million (the "Debt Payment") in partial repayment of the remaining outstanding principal and accrued interest on the Facility Notes.

Upon the closing of the Exchange and related Debt Payment, the amendments to the Facility Agreement, the Notes and the Investors' Rights Agreement, dated as of February 19, 2015, by and among the Company, Deerfield and the other parties signatory thereto, contemplated by the December 2020 Exchange Agreement that were conditional upon, among other things, the closing of the Public Offering, the filing of the Series B-2 Certificate of Designation and/or the approval for listing of the Company's common stock, including the shares issuable upon conversion of the Series B-2 Preferred Stock and exercise of the Exchange Warrants, on the Nasdaq Capital Market, became effective on January 12, 2021.

In March 2021, all shares of Series B-2 Preferred Stock converted into 4,842,699 shares of common stock.

F. Common Stock and Warrants

Authorized, Issued, and Outstanding Common Shares

As of September 30, 2022, and December 31, 2021, the Company had authorized 250,000,000 shares of common stock. Of the authorized shares, 35,411,097 and 35,325,801 shares of common stock were issued as of September 30, 2022, and December 31, 2021, respectively, and 34,501,144 and 35,005,640 shares of common stock were outstanding as of September 30, 2022, and December 31, 2021, respectively.

As of September 30, 2022, and December 31, 2021, the Company had reserved authorized shares of common stock for future issuance as follows:

	September 30, 2022	December 31, 2021
Outstanding awards under equity incentive plans	2,463,509	1,273,879
Outstanding common stock warrants	4,252,600	4,252,600
Possible future issuances under equity incentive plans	4,414,406	4,209,935
Possible future issuances under employee stock purchase plans	1,445,213	1,500,000
Total common shares reserved for future issuance	12,575,728	11,236,414

Common Stock Activity

The following table summarizes common stock activity for the nine months ended September 30, 2022:

	Shares of Common Stock
Balance as of January 1, 2022	35,005,640
Common stock issued as compensation to third-parties	7,649
Common stock repurchased as a result of the Stock Repurchase Plan	(589,792)
Balance as of March 31, 2022	34,423,497
Common stock issued as compensation to third-parties	11,030
Common stock issued as a result of the Employee Stock Purchase Plan	54,787
Balance as of June 30, 2022	34,489,314
Common stock issued as compensation to third-parties	11,830
Balance as of September 30, 2022	34,501,144

Warrants

On June 2, 2014, pursuant to the terms of the Deerfield Facility Agreement, the Company issued the Deerfield Warrant to purchase 14,423,076 shares of Series D Preferred (Note C). The Company recorded the fair value of the Deerfield Warrant as a debt discount and a warrant liability. The Deerfield Warrant, if unexercised, expires on the earlier of June 2, 2024, or upon a liquidation event. Upon completion of the Company's initial public offering (the "IPO"), the Deerfield Warrant automatically converted into a warrant to purchase 1,923,077 shares of the Company's common stock at an exercise price of $5.85 per share. After giving effect to the Reverse Stock Split effected in December 2020, the exercise price of the Deerfield Warrant became $93.60 and the shares of the Company's common stock issuable upon exercise of the Deerfield Warrant became 120,192 shares of common stock. As a result of the January 2021 Inducement Transaction (discussed below) the anti-dilution provisions within the Deerfield Warrant were triggered and the exercise price was reduced from $93.60 per share to $46.25 per share. In addition, as a result of the June 2021 Inducement Transaction (discussed below) the anti-dilution provision within the Deerfield Warrant were triggered and the exercise price was reduced from $46.25 per share to $38.34 per share. The Company amortized the debt discount over the term of the Deerfield Convertible Note and the expense was recorded as interest expense related to amortization of debt issuance costs and discount in the statements of operations. The Deerfield Convertible Note was extinguished in February 2021 and the remaining debt discount was written off and recognized as a loss on extinguishment of debt.

The Company determined that the Deerfield Warrant should be recorded as a liability and stated at fair value at each reporting period upon inception. As stated above, upon completion of the IPO, the Deerfield Warrant automatically converted into warrants to purchase the Company's common stock. The Deerfield Warrant remains classified as a liability and is recorded at fair value at each reporting period since it can be settled in cash. Changes to the fair value of the warrant liability are recorded through the unaudited condensed statements of operations as a fair value adjustment (Note H).

In connection with the APADAZ License Agreement, in October 2018, the Company issued to KVK a warrant to purchase up to 500,000 shares of common stock of the Company at an exercise price of $2.30 per share, which reflected the closing price of the Company's common stock on the Nasdaq Stock Market on the execution date of the APADAZ License Agreement (the "KVK Warrant"). The KVK Warrant is initially not exercisable for any shares of common stock. Upon the achievement of each of four specified milestones under the KVK Warrant, the KVK Warrant will become exercisable for an additional 125,000 shares, up to an aggregate of 500,000 shares of the Company's common stock. The exercise price and the number and type of shares underlying the KVK Warrant are subject to adjustment in the event of specified events, including a reclassification of the Company's common stock, a subdivision or combination of the Company's common stock, or in the event of specified dividend payments. The KVK Warrant is exercisable until October 24, 2023. Upon exercise, the aggregate exercise price may be paid, at KVK's election, in cash or on a net issuance basis, based upon the fair market value of the Company's common stock at the time of exercise. After giving effect to the reverse stock split effected in December 2020, the exercise price of the KVK Warrant became $36.80 and the shares of common stock issuable upon exercise of the KVK Warrant became 31,250 shares of common stock.

The Company determined that, since KVK qualifies as a customer under ASC 606, the KVK Warrant should be recorded as a contract asset and recognized as contra-revenue as the Company recognizes revenue from the APADAZ License Agreement. In addition, the Company determined that the KVK Warrant qualifies as a derivative under ASC 815 and should be recorded as a liability and stated at fair value each reporting period. The Company calculates the fair value of the KVK Warrant using a probability-weighted Black-Scholes option pricing model. Changes in fair value resulting from changes in the inputs to the Black Scholes model are accounted for as changes in the fair value of the derivative under ASC 815 and are recorded as fair value adjustment related to derivative and warrant liability in the unaudited condensed statements of operations. Changes in the number of shares that are expected to be issued are treated as changes in variable consideration under ASC 606 and are recorded as a change in contract asset on the unaudited condensed balance sheets. As of September 30, 2022, and December 31, 2021, a contract asset of $0.4 million is recorded in other long-term assets on the unaudited condensed consolidated balance sheets related to the KVK Warrant.

Pre-Funded Warrants

On January 12, 2021, pursuant to the terms of the Underwriting Agreement, the Company issued pre-funded warrants to purchase 926,844 shares of the Company's common stock to specified investors in the Public Offering. Each pre-funded warrant had an initial exercise price per share equal to $0.0001. The pre-funded warrants were immediately exercisable. The pre-funded warrants were exercisable, at the option of each holder, in whole or in part, by delivering to the Company a duly executed exercise notice accompanied by payment in full for the number of shares of common stock purchased upon such exercise. In lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the aggregate exercise price, the holder was able to elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants. In January 2021, all pre-funded warrants were exercised for 926,841 shares of common stock and gross proceeds of approximately $72.

Warrants to Purchase Common Stock

On January 12, 2021, pursuant to the terms of the Underwriting Agreement and December 2020 Exchange Agreement, the Company issued warrants to purchase 12,078,361 shares of the Company's common stock (collectively, the "Offering Warrants") in the Public Offering and in connection with the transactions contemplated under the December 2020 Exchange Agreement. The Offering Warrants were immediately exercisable and expire on the fifth anniversary of their issuance date, at an exercise price per share of common stock equal to $6.50 per share. The Offering Warrants are exercisable, at the option of each holder, in whole or in part, by delivering to the Company a duly executed exercise notice, provided that payment in full for the number of shares of the Company's common stock purchased upon such exercise is delivered to the Company in accordance with the terms of the Offering Warrants. In lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Offering Warrants. A holder (together with its affiliates) may not exercise any portion of the Offering Warrant to the extent that the holder and its affiliates and any other person or entities with which such holder would constitute a Section 13(d) "group" would own more than 4.99% of the Company's outstanding common stock immediately after exercise. Except as otherwise provided in the Offering Warrants or by virtue of such holder's ownership of shares of the Company's common stock, the holders of the Offering Warrants do not have the rights or privileges of holders of common stock with respect to the shares of common stock underlying the Offering Warrants, including any voting rights, until they exercise their Offering Warrants. The Offering Warrants provide that holders have the right to participate in distributions or dividends paid on the Company's common stock. In the event of a fundamental transaction, as described in the Offering Warrants and generally including any reorganization, recapitalization or reclassification of the Company's common stock, the sale, transfer or other disposition of all or substantially all of the Company's properties or assets, the Company's consolidation or merger with or into another person, the acquisition of more than 50% of the Company's outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by the Company's outstanding common stock, the holders of the Offering Warrants will be entitled to receive upon exercise of the Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Offering Warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by the Company's board of directors, the holders of the warrants have the right to require the Company or a successor entity to redeem the Offering Warrants for cash in the amount of the Black Scholes value of the unexercised portion of the Offering Warrants on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not approved by the Company's board of directors, the holders of the Offering Warrants have the right to require the Company or a successor entity to redeem the Offering Warrants in the amount of the Black Scholes value of the unexercised portion of the Offering Warrants on the date of the consummation of the fundamental transaction payable in the form of consideration paid to the holders of common stock in such fundamental transaction. The Offering Warrants meet the equity classification requirements and thus are recorded in additional paid-in capital on the unaudited condensed balance sheets. As of September 30, 2022, 3,461,858 Offering Warrants have been exercised for 3,030,881 shares of common stock and gross proceeds of approximately $16.9 million. These amounts are exclusive of the Offering Warrants exercised as part of the January 2021 Inducement Transaction discussed below.

Underwriter Warrant

On January 12, 2021, pursuant to the terms of the Underwriting Agreement, the Company issued to the Underwriter a warrant to purchase 806,932 shares of the Company's common stock (the "Underwriter Warrant"). The Underwriter Warrant is subject to substantially the same terms and conditions as the Warrants, provided that the exercise price for the Underwriter Warrant is $8.125 per share. If the Underwriter exercises any additional portion of its over-allotment option, then the Company shall issue the Underwriter an additional Underwriter Warrant exercisable for a number of shares of common stock equal to 5.0% of the number of shares of common stock issued in such over-allotment exercise (including the shares of common stock issuable upon the exercise of any Warrants issued in connection therewith). In connection with the closing of the Underwriter's partial exercise of its over-allotment option, on February 3, 2021, the Underwriter was issued an additional warrant to purchase 18,702 shares of common stock. As of September 30, 2022, 400,000 Underwriter Warrants have been exercised for 400,000 shares of common stock and gross proceeds of approximately $3.3 million.

January 2021 Warrant Exercise Inducement Letters and Issuance of Warrants

On January 26, 2021, the Company entered into warrant exercise inducement offer letters ("January 2021 Inducement Transaction") with certain holders of warrants issued in the Public Offering discussed above (the "Existing Warrants") (collectively, the "Exercising Holders") pursuant to which such holders agreed to exercise for cash their Existing Warrants to purchase 6,620,358 shares of the Company's common stock in exchange for the Company's agreement to issue new warrants (the "January 2021 Inducement Warrants") on substantially the same terms as the Existing Warrants, except as set forth in the following sentence, to purchase up to 7,944,430 shares of the Company's common stock, which is equal to 120% of the number of shares of the Company's common stock issued upon exercise of the Existing Warrants. The purchase price of the January 2021 Inducement Warrants was $0.125 per share underlying each January 2021 Inducement Warrant, and the January 2021 Inducement Warrants have an exercise price of $6.36 per share. The Company received aggregate gross proceeds of approximately $44.0 million from the exercise of the Existing Warrants by the Exercising Holders and the sale of the January 2021 Inducement Warrants. The Company engaged Roth as its exclusive placement agent in connection with these transactions and paid Roth a fee equal to 6% of gross proceeds from the exercise of the Existing Warrants by the Exercising Holders and the sale of the January 2021 Inducement Warrants. As a result of this transaction the anti-dilution provisions contained with the Deerfield Warrant were triggered and the exercise price of the Deerfield Warrant was reduced from $93.60 per share to $46.25 per share.

The January 2021 Inducement Warrants were immediately exercisable and expire on the fifth anniversary of their issuance date, at an exercise price per share of common stock equal to $6.36 per share. The January 2021 Inducement Warrants are exercisable, at the option of each holder, in whole or in part, by delivering to the Company a duly executed exercise notice, provided that payment in full for the number of shares of the Company's common stock purchased upon such exercise is delivered to the Company in accordance with the terms of the January 2021 Inducement Warrants. In lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the warrants. A holder (together with its affiliates) may not exercise any portion of the January 2021 Inducement Warrant to the extent that the holder and its affiliates and any other person or entities with which such holder would constitute a Section 13(d) "group" would own more than 4.99% (or, upon election by a holder prior to the issuance of its January 2021 Inducement Warrants, 9.99%) of the Company's outstanding common stock immediately after exercise. Except as otherwise provided in the January 2021 Inducement Warrants or by virtue of such holder's ownership of shares of the Company's common stock, the holders of the January 2021 Inducement Warrants do not have the rights or privileges of holders of common stock with respect to the shares of common stock underlying the January 2021 Inducement Warrants, including any voting rights, until they exercise their January 2021 Inducement Warrants. The January 2021 Inducement Warrants provide that holders have the right to participate in distributions or dividends paid on the Company's common stock. In the event of a fundamental transaction, as described in the January 2021 Inducement Warrants and generally including any reorganization, recapitalization or reclassification of the Company's common stock, the sale, transfer or other disposition of all or substantially all of the Company's properties or assets, the Company's consolidation or merger with or into another person, the acquisition of more than 50% of the Company's outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by the Company's outstanding common stock, the holders of the January 2021 Inducement Warrants will be entitled to receive upon exercise of the January 2021 Inducement Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the January 2021 Inducement Warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by the Company's board of directors, the holders of the January 2021 Inducement Warrants have the right to require the Company or a successor entity to redeem the January 2021 Inducement Warrants for cash in the amount of the Black Scholes value of the unexercised portion of the January 2021 Inducement Warrants on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not approved by the Company's board of directors, the holders of the January 2021 Inducement Warrants have the right to require the Company or a successor entity to redeem the January 2021 Inducement Warrants in the amount of the Black Scholes value of the unexercised portion of the January 2021 Inducement Warrants on the date of the consummation of the fundamental transaction payable in the form of consideration paid to the holders of common stock in such fundamental transaction. As of September 30, 2022, 1,676,921 January 2021 Inducement Warrants have been exercised for 1,676,921 shares of common stock and gross proceeds of approximately $10.7 million. These amounts are exclusive of the January 2021 Inducement Warrants exercised as part of the June 2021 Inducement Transaction discussed below.

In accordance with the January 2021 Inducement Transaction we recognized a deemed dividend of $37.4 million which is the difference between the grant date fair value of the January 2021 Inducement Warrants and the purchase price of the January 2021 Inducement Warrants. This deemed dividend is added to net loss to arrive at net loss attributable to common stockholders on the statements of operations.

June 2021 Warrant Exercise Inducement Letters and Issuance of Warrants

On June 18, 2021, the Company entered into warrant exercise inducement offer letters ("June 2021 Inducement Transaction") with certain holders of warrants issued in the January 2021 Inducement Transaction discussed above (the "January 2021 Inducement Warrants") (collectively, the "June 2021 Exercising Holders") pursuant to which such holders agreed to exercise for cash their January 2021 Inducement Warrants to purchase 6,117,509 shares of the Company's common stock in exchange for the Company's agreement to issue new warrants (the "June 2021 Inducement Warrants") on substantially the same terms as the January 2021 Inducement Warrants, except as set forth in the following sentence, to purchase up to 1,529,379 shares of the Company's common stock, which is equal to 25% of the number of shares of the Company's common stock issued upon exercise of the January 2021 Inducement Warrants. The purchase price of the June 2021 Inducement Warrants was $0.125 per share underlying each June 2021 Inducement Warrant, and the June 2021 Inducement Warrants have an exercise price of $16.50 per share. The Company received aggregate gross proceeds of approximately $39.1 million from the exercise of the January 2021 Inducement Warrants by the June 2021 Exercising Holders and the sale of the June 2021 Inducement Warrants. The Company engaged Roth as its exclusive placement agent in connection with these transactions and paid Roth a fee equal to 6% of gross proceeds from the exercise of the January 2021 Inducement Warrants by the June 2021 Exercising Holders and the sale of the June 2021 Inducement Warrants. As a result of this transaction the anti-dilution provisions contained with the Deerfield Warrant were triggered and the exercise price of the Deerfield Warrant was reduced from $46.25 per share to $38.34 per share.

The June 2021 Inducement Warrants were immediately exercisable and expire on December 31, 2026, at an exercise price per share of common stock equal to $16.50 per share. The June 2021 Inducement Warrants are exercisable, at the option of each holder, in whole or in part, by delivering to the Company a duly executed exercise notice, provided that payment in full for the number of shares of the Company's common stock purchased upon such exercise is delivered to the Company in accordance with the terms of the June 2021 Inducement Warrants. In lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the warrants. A holder (together with its affiliates) may not exercise any portion of the June 2021 Inducement Warrant to the extent that the holder and its affiliates and any other person or entities with which such holder would constitute a Section 13(d) "group" would own more than 4.99% (or, upon election by a holder prior to the issuance of its June 2021 Inducement Warrants, 9.99%) of the Company's outstanding common stock immediately after exercise. Except as otherwise provided in the June 2021 Inducement Warrants or by virtue of such holder's ownership of shares of the Company's common stock, the holders of the June 2021 Inducement Warrants do not have the rights or privileges of holders of common stock with respect to the shares of common stock underlying the June 2021 Inducement Warrants, including any voting rights, until they exercise their June 2021 Inducement Warrants. The June 2021 Inducement Warrants provide that holders have the right to participate in distributions or dividends paid on the Company's common stock. In the event of a fundamental transaction, as described in the June 2021 Inducement Warrants and generally including any reorganization, recapitalization or reclassification of the Company's common stock, the sale, transfer or other disposition of all or substantially all of the Company's properties or assets, the Company's consolidation or merger with or into another person, the acquisition of more than 50% of the Company's outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by the Company's outstanding common stock, the holders of the June 2021 Inducement Warrants will be entitled to receive upon exercise of the June 2021 Inducement Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the June 2021 Inducement Warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by the Company's board of directors, the holders of the June 2021 Inducement Warrants have the right to require the Company or a successor entity to redeem the June 2021 Inducement Warrants for cash in the amount of the Black Scholes value of the unexercised portion of the June 2021 Inducement Warrants on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not approved by the Company's board of directors, the holders of the June 2021 Inducement Warrants have the right to require the Company or a successor entity to redeem the June 2021 Inducement Warrants in the amount of the Black Scholes value of the unexercised portion of the June 2021 Inducement Warrants on the date of the consummation of the fundamental transaction payable in the form of consideration paid to the holders of common stock in such fundamental transaction. As of September 30, 2022, no June 2021 Inducement Warrants have been exercised.

In accordance with the June 2021 Inducement Transaction we recognized a deemed dividend of $16.9 million which is the difference between the grant date fair value of the June 2021 Inducement Warrants and the purchase price of the June 2021 Inducement Warrants. This deemed dividend is added to net loss to arrive at net loss attributable to common stockholders on the unaudited condensed consolidated statements of operations.

G. Stock-Based Compensation

The Company maintains a stock-based compensation plan (the “Incentive Stock Plan”) that governs stock awards made to employees and directors prior to completion of the IPO.

In November 2014, the Board of Directors of the Company ("the Board"), and in April 2015, the Company’s stockholders, approved the Company’s 2014 Equity Incentive Plan (the “2014 Plan”), which became effective in April 2015. The 2014 Plan provides for the grant of stock options, other forms of equity compensation, and performance cash awards. In June 2021, the Company's stockholders approved an Amended and Restated 2014 Equity Incentive Plan (the "A&R 2014 Plan"), following its adoption by the Board in April 2021, which among other things added 4,900,000 shares to the maximum number of shares of common stock to be issued under the plan and extended the annual automatic increases (discussed further below) until January 1, 2031 and eliminated individual grant limits that applied under the 2014 Plan to awards that were intended to comply with the exemption for "performance-based compensation" under Code Section 162(m). The maximum number of shares of common stock that may be issued under the A&R 2014 Plan is 6,889,885 as of September 30, 2022. The number of shares of common stock reserved for issuance under the A&R 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2016, and ending on and including January 1, 2031, by 4% of the total number of shares of the Company’s capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Board. Pursuant to the terms of the 2014 Plan, on January 1, 2022, the common stock reserved for issuance under the 2014 Plan automatically increased by 1,400,225 shares.

During the three and nine months ended September 30, 2022, and 2021, no stock options were exercised.

In June 2021, the Company's stockholders approved an Employee Stock Purchase Plan (the "ESPP"), following its adoption by the Board in April 2021. The maximum number of shares of common stock that may be issued under the ESPP is 1,500,000. The first offering period under the ESPP began on October 1, 2021, and the first purchase date occurred on May 31, 2022. As of September 30, 2022, 54,787 shares have been issued under the ESPP.

Stock-based compensation expense recorded under the 2014 Plan, A&R 2014 Plan and ESPP is included in the following line items in the accompanying unaudited condensed consolidated statements of operations (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Research and development	$ 360	$ 201	$ 1,093	$ 630
General and administrative	551	419	2,246	983
Total stock-based compensation expense	$ 911	$ 620	$ 3,339	$ 1,613

There was no stock-based compensation expense related to performance-based awards recognized during the three months ended September 30, 2022, or 2021. There was $0.4 million of stock-based compensation expense related to performance-based awards recognized during the nine months ended September 30, 2022, and $0.4 million of stock-based compensation expense related to performance-based awards recognized during the nine months ended September 30, 2021.

H. Fair Value of Financial Instruments

The accounting standard for fair value measurements provides a framework for measuring fair value and requires disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, based on the Company's principal or, in absence of a principal, most advantageous market for the specific asset or liability.

The Company uses a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to their initial measurement. The hierarchy requires the Company to use observable inputs when available, and to minimize the use of unobservable inputs, when determining fair value. The three tiers are defined as follows:

- Level 1—Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2—Observable inputs other than quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities; and
- Level 3—Unobservable inputs that are supported by little or no market data, which require the Company to develop its own assumptions.

The carrying amounts of certain financial instruments, including cash and cash equivalents, investments and accounts payable and accrued expenses, approximate their respective fair values due to the short-term nature of such instruments.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company evaluates its financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level in which to classify them for each reporting period. This determination requires significant judgments to be made. The following table summarizes the conclusions reached regarding fair value measurements as of September 30, 2022, and December 31, 2021 (in thousands):

	Balance as of September 30, 2022	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Deerfield Warrant liability	$ 30	$ —	$ —	$ 30
Embedded Warrant Put Option	4	—	—	4
KVK Warrant liability	1	—	1	—
Total liabilities	$ 35	$ —	$ 1	$ 34
	—			
Securities:				
U.S. government-sponsored agency securities	$ 7,171	$ —	$ 7,171	$ —
Certificates of deposit	20,475	20,475	—	—
U.S. Treasury securities	9,649	9,649	—	—
Total assets	$ 37,295	$ 30,124	$ 7,171	$ —

	Balance as of December 31, 2021	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Deerfield Warrant liability	$ 288	$ —	$ —	$ 288
Embedded Warrant Put Option	18	—	—	18
KVK Warrant liability	24	—	24	—
Total liabilities	$ 330	$ —	$ 24	$ 306
Securities:				
U.S. government-sponsored agency securities	$ 4,997	$ —	$ 4,997	$ —
Certificates of deposit	490	490	—	—
U.S. Treasury securities	9,935	9,935	—	—
Total assets	$ 15,422	$ 10,425	$ 4,997	$ —

The Company's Deerfield Warrant liability, embedded Warrant Put Option and securities are measured at fair value on a recurring basis. As of September 30, 2022, and December 31, 2021, the Deerfield Warrant liability and the embedded Warrant Put Option are reported on the unaudited condensed consolidated balance sheets in derivative and warrant liability. As of September 30, 2022, and December 31, 2021, the securities are reported on the unaudited condensed consolidated balance sheets in short-term and long-term investments. The Company used a Monte Carlo simulation to value the Deerfield Warrant liability and embedded Warrant Put Option for all periods presented herein. Significant unobservable inputs used in measuring the fair value of these financial instruments included the Company's estimated enterprise value, an estimate of the timing of a liquidity or fundamental change event and a present value discount rate. Changes in the fair value of the Deerfield Warrant liability and embedded Warrant Put Option are reflected in the unaudited condensed consolidated statements of operations for the three and nine months ended September 30, 2022, and 2021, as a fair value adjustment related to derivative and warrant liability.

The derivative liability for the Deerfield Warrant was $30,000 and $288,000 at September 30, 2022, and December 31, 2021, respectively. The derivative liability for the embedded Warrant Put Option was $4,000 and $18,000 at September 30, 2022, and December 31, 2021, respectively. A 10% increase in the enterprise value would result in an increase of $13,000 in the estimated fair value of the Deerfield Warrant liability and an increase of $1,000 in the estimated fair value of the embedded Warrant Put Option liability. In addition, the Company assumed a weighted-average probability of a liquidity event occurring of approximately 25% with an estimated probability-weighted value of approximately $40.0 million and a weighted-average probability of a fundamental change event occurring of approximately 29% with an estimated probability-weighted value of approximately $555.0 million, respectively, with estimated timing in each scenario of the third quarter of 2023.

The Company's KVK Warrant liability is measured at fair value on a recurring basis. As of September 30, 2022, and December 31, 2021, the KVK Warrant liability is reported on the unaudited condensed consolidated balance sheets in derivative and warrant liability. The Company estimates the fair value of the KVK Warrant using a probability-weighted Black-Scholes option-pricing model, which requires the use of subjective assumptions, including the expected term of the warrant, the expected stock price volatility, expected dividend yield and the risk-free interest rate for the expected term of the warrant. The expected term represents the period of time the warrant is expected to be outstanding. For the KVK Warrant, the Company used an expected term equal to the contractual term of the warrant. Expected volatility is based on the Company's historical volatility since the IPO. The Company assumes no dividend yield because dividends are not expected to be paid in the near future, which is consistent with the Company's history of not paying dividends. Changes in the fair value of the KVK Warrant liability are reflected in the unaudited condensed consolidated statements of operations for the three and nine months ended September 30, 2022, and 2021, as a fair value adjustment related to derivative and warrant liability.

A reconciliation of the beginning and ending balances for the derivative and warrant liability measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Balance as of beginning of period	$ 56	$ 666	$ 306	$ 255
Adjustment to fair value	(22)	(305)	(272)	106
Balance as of end of period	$ 34	$ 361	$ 34	$ 361

I. Net Loss Per Share

For all periods presented herein, the Company did not use the two-class method to compute net loss attributable to common stockholders per share of common stock, even though it had issued securities, other than common stock, that contractually entitled the holders to participate in dividends and earnings, because these holders are not obligated to participate in a loss. The two-class method requires earnings for the period to be allocated between common stock and participating securities based upon their respective rights to receive distributed and undistributed earnings.

Under the two-class method, for periods with net income attributable to common stockholders, basic net income attributable to common stockholders per share of common stock is computed by dividing the undistributed net income attributable to shares of common stockholders by the weighted average number of shares of common stock outstanding during the period. Undistributed net income attributable to shares of common stockholders is computed by subtracting from net income the portion of current period earnings that participating securities would have been entitled to receive pursuant to their dividend rights had all of the period's earnings been distributed and subtracting the actual or deemed dividends declared. No such adjustment to earnings is made during periods with a net loss as the holders of the participating securities have no obligation to fund losses. Diluted net income attributable to common stockholders per share of common stock is computed under the two-class method by using the weighted average number of shares of common stock outstanding plus the potential dilutive effects of stock options, warrants and other outstanding convertible securities. In addition to analyzing under the two-class method, the Company analyzes the potential dilutive effect of stock options and warrants, under the treasury-stock method and other outstanding convertible securities under the if-converted method when calculating diluted income (loss) attributable to common stockholders per share of common stock, in which it is assumed that the stock options, warrants and other outstanding convertible securities convert into common stock at the beginning of the period or date of issuance, if the stock option, warrant or other outstanding convertible security was issued during the period. The Company reports the more dilutive of the approaches (two-class or treasury-stock/if-converted) as its diluted net income (loss) attributable to common stockholders per share of common stock during the period.

As noted above, for all periods presented herein, the Company did not utilize the two-class approach as the Company was in a net loss position and the holders of the participating securities have no obligation to fund losses. The Company did analyze diluted net loss attributable to common stockholders per share of common stock under the treasury-stock/if-converted method and noted that all outstanding stock options and warrants were anti-dilutive for the periods presented. For all period presented, basic net loss attributable to common stockholders per share of common stock was the same as diluted net loss attributable to common stockholders per share of common stock.

The following securities, presented on a common stock equivalent basis, have been excluded from the calculation of weighted average number of shares of common stock outstanding because their effect is anti-dilutive:

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Awards under equity incentive plans	2,463,509	1,169,379	2,463,509	1,169,379
Common stock warrants	4,252,600	4,221,350	4,252,600	4,221,350
Total securities excluded from the calculation of weighted average number of shares of common stock outstanding	6,716,109	5,390,729	6,716,109	5,390,729

A reconciliation from net loss to basic and diluted net loss attributable to common stockholders per share of common stock for the three and nine months ended September 30, 2022, and 2021, is as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Basic and diluted net loss per share of common stock:				
Net income (loss)	$ (6,616)	$ (1,759)	$ (32,522)	$ (5,852)
Less: Dividends declared or accumulated	—	—	—	(54,342)
Net (loss) income attributable to shares of common stockholders, basic and diluted	**$ (6,616)**	**$ (1,759)**	**$ (32,522)**	**$ (60,194)**
Less: Net income attributable to participating securities	—	—	—	—
Undistributed net (loss) income attributable to common stockholders, basic and diluted	**$ (6,616)**	**$ (1,759)**	**$ (32,522)**	**$ (60,194)**
Weighted average number of shares of common stock outstanding, basic and diluted	34,495	35,218	34,483	27,905
Basic and diluted net loss attributable to common stockholders per share of common stock	**$ (0.19)**	**$ (0.05)**	**$ (0.94)**	**$ (2.16)**

J. Leases

The Company has operating and finance leases for office space, laboratory facilities and various laboratory equipment, furniture and office equipment and leasehold improvements. The Company's leases have remaining lease terms of less than 1 year to approximately 4 years, some of which include options to extend the leases for up to 5 years, and some which include options to terminate the leases within 1 year.

Effective June 1, 2021, the Company agreed to sublease office space in Florida, comprised of one of the two contiguous suites, under a non-cancelable operating lease, which expires in February 2026.

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

	Three months ended September 30,		Nine months ended September 30,	
Lease Cost	**2022**	**2021**	**2022**	**2021**
Finance lease cost:				
Amortization of right-of-use assets	$ 32	$ 32	$ 96	$ 96
Interest on lease liabilities	0	2	1	9
Total finance lease cost	32	34	97	105
Operating lease cost	114	91	304	274
Short-term lease cost	53	50	155	149
Variable lease cost	13	13	39	34
Less: sublease income	(39)	(39)	(117)	(52)
Total lease costs	$ 173	$ 149	$ 478	$ 510

Supplemental cash flow information related to leases was as follows (in thousands):

	Nine months ended September 30,	
	2022	**2021**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from finance leases	$ 1	$ 9
Financing cash flows from finance leases	13	156
Operating cash flows from operating leases	381	344
Operating cash flows from short-term leases	155	149
Operating cash flows from variable lease costs	39	34
Right-of-use assets obtained in exchange for lease liabilities:		
Finance leases	$ —	$ —
Operating leases	146	—

Supplemental balance sheet information related to leases was as follows (in thousands, except weighted average remaining lease term and weighted average discount rate):

	September 30, 2022	December 31, 2021
Finance Leases		
Property and equipment, at cost	$ 1,031	$ 1,031
less: accumulated depreciation and amortization	(747)	(651)
Property and equipment, net	$ 284	$ 380
Other current liabilities	$ 7	$ 15
Other long-term liabilities	1	6
Total finance lease liabilities	$ 8	$ 21
Operating Leases		
Operating lease right-of-use assets	$ 1,068	$ 1,141
Total operating lease right-of-use assets	$ 1,068	$ 1,141
Current portion of operating lease liabilities	$ 474	$ 356
Operating lease liabilities, less current portion	956	1,232
Total operating lease liabilities	$ 1,430	$ 1,588
Weighted Average Remaining Lease Term		
Finance leases (years)	1	1
Operating leases (years)	3	4
Weighted Average Discount Rate		
Finance leases	14.3%	12.0%
Operating leases	7.2%	7.5%

Maturities of lease liabilities were as follows (in thousands):

Year Ending December 31,	Finance Leases	Operating Leases
2022 (excluding the nine months ended September 30, 2022)	$ 2	$ 131
2023	6	563
2024	—	488
2025	—	390
2026	—	30
Total lease payments	8	1,602
Less: future interest expense	0	(172)
Lease liabilities	$ 8	$ 1,430

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in Part II, Item 1A. "Risk Factors" of this Quarterly Report on Form 10-Q and Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 31, 2022, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biotechnology company focused on the discovery, development and commercialization of novel treatments for rare central nervous system, or CNS, and neurodegenerative diseases, lysosomal storage disorders and related treatment areas. We have a diverse product portfolio, combining a clinical-stage development pipeline with new drug application, or NDA, stage and commercial assets. The pipeline includes arimoclomol, an orally-delivered, first-in-class investigational product candidate for Niemann-Pick disease type C, or NPC, and KP1077, which we are developing as a treatment for idiopathic hypersomnia, or IH, a rare neurological sleep disorder, and narcolepsy. In addition, the U.S. Food and Drug Administration, or FDA, has approved AZSTARYS®, formally referred to as KP415, a once-daily treatment for attention deficit hyperactivity disorder, or ADHD, in patients age six years and older containing our prodrug, serdexmethylphenidate, or SDX, which is being commercialized by Corium, Inc., or Corium, an affiliate of Gurnet Point Capital, L.P., in the U.S. Corium was tasked by Commave Therapeutics SA (formerly known as Boston Pharmaceutical S.A.), or Commave, an affiliate of Gurnet Point Capital, L.P., to lead all commercialization activities for AZSTARYS under the AZSTARYS License Agreement (as defined below). The FDA has also approved APADAZ®, an immediate-release combination product containing benzhydrocodone, our prodrug of hydrocodone, and acetaminophen, which is being commercialized by KVK-Tech, Inc. in the U.S.

Our strategic focus on CNS/rare disease indications guides our business development efforts to expand our pipeline with the goal of developing and potentially commercializing innovative therapies for patients living with CNS/rare neurological disorders. We intend to target assets that will allow us to leverage the expertise and infrastructure that we have successfully built at KemPharm in order to mitigate risk and enhance our probability of success. In addition, we are considering external opportunities within neurology and neurodegenerative diseases, psychiatric disorders, and other rare diseases, along with adjacent or related therapeutic categories. We are seeking assets that are undergoing Phase 2 clinical trials or Phase 3 clinical trials, subject to our specific evaluation criteria, that we can in-license or acquire. If we are successful, expanding our development pipeline could be accretive to our value proposition by potentially adding new clinical data catalysts and have the potential to create incremental long-term value for shareholders. In addition, we believe that a multi-channel development program with several product candidates addressing various CNS/rare disease indications will diversify risk and potentially create an impactful portfolio of commercial-stage products in the future.

For example, in May 2022, we, through our newly formed wholly-owned subsidiary, KemPharm Denmark A/S, or KemPharm DK, entered into an Asset Purchase Agreement, or the Arimoclomol Purchase Agreement, with Orphazyme A/S in restructuring, a Danish public limited liability company, or Orphazyme. The transactions agreed to under the Arimoclomol Purchase Agreement closed on May 31, 2022. Under the terms of the Arimoclomol Purchase Agreement, KemPharm DK purchased all of the assets and operations of Orphazyme related to arimoclomol and settled all of Orphazyme's actual outstanding liabilities to its creditors with a cash payment of $12.8 million. In addition, KemPharm DK agreed to assume an estimated reserve liability of $5.2 million related to revenue generated from Orphazyme's Early Access Program in France, or the Arimoclomol EAP.

Our most advanced product candidate, arimoclomol, is intended for the treatment of NPC, a lysosomal storage disease, or LSD. NPC is a rare, genetic and progressive disease that impairs the ability of the body to recycle cholesterol and other types of lipids, resulting in damage to the body's tissues, including the brain. Symptoms of NPC usually occur during mid to late childhood, and include difficulties in swallowing, loss of speech and cognition, motor coordination and ambulation. In more aggressive forms, NPC is frequently fatal by the time patients reach their twenties. We estimate the incidence of NPC to be one in 100,000 live births. Based on these incidence rates, the number of NPC patients in the United States and in Europe is estimated to be approximately 1,800 individuals. Of these, we estimate that approximately 1,100 individuals have been diagnosed, of which approximately 300 are in the United States and approximately 800 are in Europe. However, diagnostic challenges may affect the number of potential patients, and we believe that the availability of treatment options could increase awareness of the disease and assist in identifying more cases. We believe that there is a significant unmet need for new treatments for NPC due to the side effects, limited availability and efficacy of the existing treatment options.

Arimoclomol is currently available to NPC patients in the United States through our early access program, or EAP, with fifteen active treatment sites as of September 30, 2022. Early access and other compassionate use programs for the treatment of NPC are also available in France, Germany, Denmark, Italy, Switzerland, and the UK, and we may in the future establish early access programs or compassionate use programs in other locations. Both the FDA and the European Medicines Agency, or EMA, have granted arimoclomol orphan drug designation for NPC. The FDA has also granted arimoclomol fast track designation in NPC, has designated arimoclomol as a breakthrough therapy in NPC, and has granted arimoclomol a rare pediatric disease designation in NPC, potentially entitling us to a priority review voucher if arimoclomol is approved in NPC. In June 2021, the FDA issued a Complete Response Letter to the previous sponsor of arimoclomol, Orphazyme. We intend to resubmit the arimoclomol NDA to the FDA as early as the third quarter of 2023.

We also intend to advance our pipeline of prodrug product candidates for the treatment of IH and other CNS/rare diseases, and we reported top-line data from a Phase 1 proof-of-concept study of SDX in the fourth quarter of 2021 and final data for the Phase 1 proof-of-concept study of SDX in the first quarter of 2022. The proof-of-concept study was a dose-escalation study to determine the pharmacokinetics, pharmacodynamic stimulant effects, and safety of single oral doses of SDX in subjects with a history of high-dose stimulant use. The full data set, which builds upon top-line data previously reported in the fourth quarter of 2021, affirmed that 240 mg and 360 mg doses of SDX were well-tolerated and produced d-MPH exposure that appeared to increase proportionally with dose. Mean d-MPH plasma concentrations demonstrated a gradual increase after SDX administration, reaching a broad peak from eight to twelve hours post-dose, followed by a shallow decline thereafter. Increased wakefulness, alertness, hypervigilance, and insomnia effects were reported by study participants, which suggests that SDX produced targeted pharmacodynamic effects that could benefit patients with IH and other sleep disorders.

In January 2022, we announced that we have selected KP1077 for the treatment of IH and narcolepsy as our next clinical development candidate. KP1077 utilizes SDX, our prodrug of d-MPH, as its active pharmaceutical ingredient. During the first quarter of 2022, we initiated a Phase 1 clinical trial comparing the cardiovascular safety of SDX to immediate-release and long-acting formulations of RITALIN®, a commonly prescribed CNS stimulant. In September 2022, we announced topline data from our exploratory Phase 1 clinical trial confirming the relative cardiovascular effects and pharmacokinetics of SDX compared to immediate-release and long-acting formulations of Ritalin. Based on the data, we believe the initial dosing strengths for the planned Phase 2 clinical trial of KP1077 will be well-tolerated while providing higher overall exposures to d-MPH compared to other methylphenidate products that are often used off-label as a treatment for IH. In addition, on May 5, 2022, we announced that we submitted an investigational new drug, or IND, application with the U.S. Food and Drug Administration, or FDA, seeking permission to commence a clinical program to evaluate KP1077 in IH. Upon clearance of the IND, we plan to initiate a Phase 2 clinical trial of KP1077 in IH, in the United States, as early as the fourth quarter of 2022, with a second trial in narcolepsy anticipated to begin soon after the initiation of the IH clinical trial.

In May 2021, we announced that SDX, our proprietary prodrug of d-MPH and the primary active pharmaceutical ingredient, or API, in AZSTARYS, was classified as a Schedule IV controlled substance by the U.S. Drug Enforcement Administration, or DEA. AZSTARYS is classified as a Schedule II controlled substance as it includes a 70:30 mixture of SDX (Schedule IV) and d-MPH (Schedule II), respectively.

In March 2021, we announced that the FDA approved the New Drug Application, or NDA, for AZSTARYS, a once-daily product for the treatment of ADHD in patients ranging from six years and older. Commave has licensed the commercial rights for AZSTARYS as provided by the AZSTARYS License Agreement, and has tasked Corium with leading all commercialization activities for AZSTARYS in the United States. Corium commercially launched AZSTARYS in the United States during the third quarter of 2021. In December 2021, Commave sublicensed commercialization rights for AZSTARYS in greater China to Shanghai Ark Biopharmaceutical Ltd.

We employ our proprietary Ligand Activated Therapy, or LAT, platform technology to discover and develop prodrugs that are new molecules that may potentially improve one or more of the attributes of approved drugs, such as enhanced bioavailability, extended duration of action, increased safety and reduced susceptibility to abuse. A prodrug is a precursor chemical compound of a drug that is inactive or less than fully active, which is then converted in the body to the active form of the drug through a normal metabolic process. Where possible, we seek, to develop prodrugs that will be eligible for approval under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or the FFDCA, otherwise known as a 505(b)(2) NDA, which allows us to submit an NDA that relies on the FDA's previous findings of safety and effectiveness for one or more approved products, if we demonstrate such reliance is scientifically appropriate.

We continue to seek opportunities to expand our pipeline of product candidates through our business development efforts, and by employing our LAT platform technology and development expertise to develop additional product candidates that address significant unmet medical needs in therapeutic indications which have few existing product options. We believe our prodrug product candidates may be eligible for composition-of-matter patent protection and we intend to use the 505(b)(2) NDA pathway when available, which we believe has the potential to reduce drug development time and expense.

We have historically had minimal positive net cash flows from operations. Our cash flows used in operations for the nine months ended September 30, 2022, and 2021, were $(14.3) million and $11.3 million, respectively. However, the positive net cash flows from operations for the nine months ended September 30, 2021, were primarily due to an adjustment to reconcile net loss to net cash used in operations of approximately $16.1 million related to a loss on extinguishment of debt during the period.

We expect to continue to incur significant expenses and minimal positive net cash flows from operations or negative net cash flows from operations for the foreseeable future, and those expenses and losses may fluctuate significantly from quarter-to-quarter and year-to-year. We anticipate that our expenses will fluctuate substantially as we:

- continue our ongoing preclinical studies, clinical trials and our product development activities for our pipeline of product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue research and preclinical development and initiate clinical trials of our product candidates;
- seek to discover and develop additional product candidates either internally or in partnership with other pharmaceutical companies;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio; and
- incur additional legal, accounting and other expenses in operating as a public company.

Our Product Candidates and Approved Products

We have employed our proprietary LAT platform technology to create a portfolio of approved products that we believe will offer, and product candidates that we believe have the potential to offer, significant improvements over currently available FDA-approved drugs. We also strive to acquire product candidates that we feel complement our portfolio, for example, in May 2022, we purchased all of the assets and operations of Orphazyme related to arimoclomol.

A selection of our product candidates and approved products are summarized in the table below:

Selected KemPharm Partnered and Other Development Assets

Parent Drug (Effect Profile) (Indication)	Product Candidate / Product (Status)	Development Status	Next Milestone(s)
Arimoclomol (ER) (NPC)	Arimoclomol	NDA Preparation	NDA Submission - as early as Q3 2023
Methylphenidate (ER) (IH)	KP1077*	Clinical - Phase 2	Initiation of Pivotal Phase 2 Trial - as early as YE 2022
Methylphenidate (ER) (Narcolepsy Types I and II)	KP1077*	Clinical - Phase 2	Initiation of Pivotal Phase 2 Trial - as early as YE 2022
Methylphenidate (ER) (SUD)	KP879	Clinical - Phase 2	External funding and collaborations
Methylphenidate (ER) (ADHD)	AZSTARYS (Partnered)	FDA Approved	Tracking Payor Contracts and TRx's
Hydrocodone/APAP (IR) (Pain)	APADAZ (Partnered)	FDA Approved	Tracking Payor Contracts and TRx's

* This product candidate is subject to a right of first negotiation upon completion of a Phase 1 proof-of-concept study in favor of Commave under the terms of the AZSTARYS License Agreement, but is not currently licensed to Commave, thereunder.

These anticipated milestones are based on information currently available to us. Our current plans and expectations are subject to a number of uncertainties, risks, and other important factors that could materially impact our plans, including risks which are not solely within our control. See Part II, Item 1A. "Risk Factors" of this Quarterly Report on Form 10-Q and Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 31, 2022.

Third-Party Agreements

AZSTARYS License Agreement

In September 2019, we entered into a collaboration and license agreement, or the AZSTARYS License Agreement, with Commave. Under the AZSTARYS License Agreement, we granted to Commave an exclusive, worldwide license to develop, manufacture and commercialize our product candidates containing SDX and d-MPH, including AZSTARYS, KP484, and, at the option of Commave, KP879, KP922 or any other product candidate developed by us containing SDX and developed to treat ADHD or any other central nervous system disorder, or the Additional Product Candidates and, collectively with AZSTARYS and KP484, the Licensed Product Candidates.

Under the terms of the AZSTARYS License Agreement, we granted Commave an exclusive, worldwide license to commercialize and develop the Licensed Product Candidates; provided that such license shall apply to an Additional Product Candidate only if Commave exercises its option under the AZSTARYS License Agreement related thereto. If Commave exercises its option related to any Additional Product Candidate under the AZSTARYS License Agreement, the parties are obligated to negotiate in good faith regarding the economic terms of such Additional Product Candidate. We also granted to Commave a right of first refusal to acquire, license or commercialize any Additional Product Candidate, with such right of first refusal expiring upon the acceptance of a new drug application for such Additional Product Candidate. We also granted Commave a right of first negotiation and a right of first refusal, subject to specified exceptions, for any assignment of our rights under the AZSTARYS License Agreement.

Pursuant to the AZSTARYS License Agreement, Commave paid us an upfront payment of $10.0 million and agreed to pay up to $63.0 million in milestone payments upon the occurrence of specified regulatory milestones related to AZSTARYS, including FDA approval and specified conditions with respect to the final approval label, and KP484. In addition, Commave agreed to make additional payments upon the achievement of specified U.S. sales milestones of up to $420.0 million in the aggregate. Further, Commave will pay us quarterly, tiered royalty payments ranging from a percentage in the high single digits to the mid-twenties of Net Sales (as defined in the AZSTARYS License Agreement) in the United States and a percentage in the low to mid-single digits of Net Sales in each country outside the United States, in each case subject to specified reductions under certain conditions as described in the AZSTARYS License Agreement. Commave is obligated to make such royalty payments on a product-by-product basis until expiration of the Royalty Term (as defined in the AZSTARYS License Agreement) for the applicable product.

In April 2021, we entered into Amendment No. 1 to the AZSTARYS License Agreement, or the AZSTARYS Amendment. Pursuant to the AZSTARYS Amendment, we agreed to modify the compensation terms of the AZSTARYS License Agreement. In addition, the AZSTARYS Amendment increased the total remaining future regulatory and sales milestone payments related to AZSTARYS up to an aggregate of $590.0 million in payments upon the occurrence of specified regulatory milestones related to AZSTARYS and upon the achievement of specified U.S. net sales milestones. Further, Commave agreed to pay us quarterly, tiered royalty payments ranging from a percentage in the high single digits to the mid-twenties of Net Sales (as defined in the AZSTARYS License Agreement) in the United States and a percentage in the low to mid-single digits of Net Sales in each country outside the United States, in each case subject to specified reductions under certain conditions, including with respect to the final approval label, as described in the AZSTARYS License Agreement. Commave is obligated to make such royalty payments on a product-by-product basis until expiration of the royalty term for the applicable product.

Pursuant to the AZSTARYS Amendment, we also agreed to modify Commave's right of first refusal such that our product candidate, KP922, is no longer subject to Commave' right of first refusal to acquire, license or commercialize any Additional Product Candidate. Commave's right of first refusal shall only apply to any Additional Product Candidate which contains SDX, with such right of first refusal expiring upon the acceptance of an NDA for such Additional Product Candidate containing SDX.

Commave agreed to be responsible for and reimburse us for all of development, commercialization and regulatory expenses for the Licensed Product Candidates, subject to certain limitations as set forth in the AZSTARYS License Agreement.

The AZSTARYS License Agreement will continue on a product-by-product basis (i) until expiration of the royalty term for the applicable Licensed Product Candidate in the United States and (ii) perpetually for all other countries. Commave may terminate the AZSTARYS License Agreement at its convenience upon prior written notice prior to regulatory approval of any Licensed Product Candidate or upon prior written notice after regulatory approval of any Licensed Product Candidate. We may terminate the AZSTARYS License Agreement in full if Commave, any of its sublicensees or any of its or their affiliate challenges the validity of any Licensed Patent (as defined in the AZSTARYS License Agreement) and such challenge is not required under a court order or subpoena and is not a defense against a claim, action or proceeding asserted by us. Either party may terminate the AZSTARYS License Agreement (i) upon a material breach of the AZSTARYS License Agreement by the other party, subject to a cure period, or (ii) if the other party encounters bankruptcy or insolvency. Upon a Serious Material Breach (as defined in the AZSTARYS License Agreement) by us, subject to a cure period, Commave may choose not to terminate the AZSTARYS License Agreement and instead reduce the milestone and royalty payments owed to us. Upon termination, all licenses and other rights granted by us to Commave pursuant to the AZSTARYS License Agreement would revert to us. During the term of the AZSTARYS License Agreement, we may not develop or commercialize any Competing Product (as defined in the AZSTARYS License Agreement).

Other Third-Party Agreements

Under our March 2012 termination agreement with Aquestive, Aquestive has the right to receive a royalty amount equal to 10% of any value generated by AZSTARYS, KP484, KP879 or KP1077, and any product candidates containing SDX, including royalty payments on any license of AZSTARYS, KP484, KP879 or KP1077, the sale of AZSTARYS, KP484, KP879 or KP1077 to a third party, the commercialization of AZSTARYS, KP484, KP879 or KP1077 and the portion of any consideration that is attributable to the value of AZSTARYS, KP484, KP879 or KP1077 and paid to us or our stockholders in a change of control transaction.

In July 2020, we entered into the Corium Consulting Agreement under which Corium and Commave, respectively, engaged us to guide the product development and regulatory activities for certain current and potential future products in their portfolio, as well as continue supporting preparation for the potential commercial launch of AZSTARYS. Under the Corium Consulting Agreement, we were entitled to receive payments from Corium of up to $15.6 million, $13.6 million of which was earned in monthly installments through March 31, 2022, and paid in arrears. The remaining $2.0 million was conditioned upon the approval by the FDA of the NDA for Corium's product candidate, ADLARITY, which was approved in the first quarter of 2022. Corium also agreed to be responsible for and reimburse us for all development, commercialization and regulatory expenses incurred as part of the performance of the consulting services.

Results of Operations

Comparison of the three months ended September 30, 2022 and 2021 (in thousands):

	Three months ended September 30,		Period-to-Period Change
	2022	2021	
Revenue, net	$ 2,874	$ 1,965	$ 909
Operating expenses:			
Cost of revenue	141	—	141
Research and development	5,385	2,239	3,146
General and administrative	3,974	1,948	2,026
Total operating expenses	9,500	4,187	5,313
Loss from operations	(6,626)	(2,222)	(4,404)
Other (expense) income:			
Interest expense on principal	(124)	(6)	(118)
Fair value adjustment related to derivative and warrant liability	22	332	(310)
Interest and other income, net	79	137	(58)
Total other (expense) income	(23)	463	(486)
Loss before income taxes	(6,649)	(1,759)	(4,890)
Income tax benefit	33	—	33
Net loss	$ (6,616)	$ (1,759)	$ (4,857)
Deemed dividend	—	—	—
Net loss attributable to common stockholders	$ (6,616)	$ (1,759)	$ (4,857)

Net Loss Attributable to Common Stockholders

Net loss attributable to common stockholders for the three months ended September 30, 2022, was $6.6 million compared to net loss attributable to common stockholders of $1.8 million for the three months ended September 30, 2021, a change of $4.9 million. The change was primarily attributable to a change in loss from operations of $4.4 million, a change in fair value adjustment related to derivative and warrant liability of $0.3 million, and a change in net interest expense and other items of $0.2 million.

Revenue

Revenue for the three months ended September 30, 2022, was $2.9 million, an increase of $0.9 million compared to revenue of $2.0 million for the three months ended September 30, 2021. The increase was primarily attributable to an increase in revenue from the Arimoclomol EAP of $2.3 million, partially offset by a decrease in revenue from the Corium Consulting Agreement.

Cost of Revenue

Cost of revenue for the three months ended September 30, 2022, was $0.1 million, an increase of $0.1 million compared to no cost of revenue for the three months ended September 30, 2021. The increase was primarily attributable to cost of goods sold under the Arimoclomol EAP.

Research and Development

Research and development expenses increased by $3.2 million, from $2.2 million for the three months ended September 30, 2021, to $5.4 million for the three months ended September 30, 2022. This increase was primarily attributable to an increase in third-party research and development costs of $2.4 million, an increase in personnel-related costs of $0.5 million and an increase in other research and development costs of $0.3 million.

General and Administrative

General and administrative expenses increased by $2.0 million, from $1.9 million for the three months ended September 30, 2021, to $4.0 million for the three months ended September 30, 2022. This increase was primarily attributable to an increase in personnel-related costs of $0.9 million, an increase in professional fees of $0.7 million and an increase in other general and administrative costs of $0.3 million.

Other (Expense) Income

Other (expense) income changed by $480,000, from $460,000 of income for the three months ended September 30, 2021, to $20,000 of expense for the three months ended September 30, 2022. This period-to-period change was primarily attributable to a change in fair value adjustment related to derivative and warrant liability of $310,000 and a change in net interest expense and other items of $170,000.

Comparison of the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine months ended September 30,		Period-to-
	2022	2021	Period Change
Revenue, net	$ 8,139	$ 26,068	$ (17,929)
Operating expenses:			
Cost of revenue	200	2,000	(1,800)
Research and development	13,262	7,352	5,910
General and administrative	10,266	6,145	4,121
Acquired in-process research and development	17,663	—	17,663
Total operating expenses	41,391	15,497	25,894
(Loss) income from operations	(33,252)	10,571	(43,823)
Other (expense) income:			
Loss on extinguishment of debt	—	(16,096)	16,096
Interest expense related to amortization of debt issuance costs and discount	—	(150)	150
Interest expense on principal	(165)	(221)	56
Fair value adjustment related to derivative and warrant liability	295	(92)	387
Interest and other (expense) income, net	(152)	136	(288)
Total other (expense) income	(22)	(16,423)	16,401
Loss before income taxes	(33,274)	(5,852)	(27,422)
Income tax benefit	752	—	752
Net loss	$ (32,522)	$ (5,852)	$ (26,670)
Deemed dividend	—	(54,342)	54,342
Net loss attributable to common stockholders	$ (32,522)	$ (60,194)	$ 27,672

Net Loss Attributable to Common Stockholders

Net loss attributable to common stockholders for the nine months ended September 30, 2022, was $32.5 million compared to net loss attributable to common stockholders of $60.2 million for the nine months ended September 30, 2021, a change of $27.7 million. The change was primarily attributable to a deemed dividend, recognized as a result of the January 2021 Inducement Transaction and June 2021 Inducement Transaction, totaling $54.3 million which did not recur in 2022, a net loss on extinguishment of debt of $16.1 million in 2021 that did not recur in 2022, a change in fair value adjustment related to derivative and warrant liability of $0.4 million, and an income tax benefit of $0.8 million, partially offset by a change in (loss) income from operations of $43.8 million.

Revenue

Revenue for the nine months ended September 30, 2022, was $8.1 million, a decrease of $17.9 million compared to revenue of $26.1 million for the nine months ended September 30, 2021. The decrease was primarily attributable to a decrease in revenue from the AZSTARYS License Agreement and Corium Consulting Agreement; partially offset by an increase in revenue from the Arimoclomol EAP and other consulting arrangements.

Cost of Revenue

Cost of revenue for the nine months ended September 30, 2022, was $0.2 million, a decrease of approximately $1.8 million compared to cost of revenue of $2.0 million for the nine months ended September 30, 2021. The decrease was primarily attributable to a decrease in royalty payments to Aquestive related to revenue from the AZSTARYS License Agreement due to the regulatory milestone revenue earned in the first and second quarters of 2021, partially offset by royalties payable to Aquestive for the AZSTARYS License Agreement royalty revenue and cost of goods sold under the Arimoclomol EAP.

Research and Development

Research and development expenses increased by $5.9 million, from $7.4 million for the nine months ended September 30, 2021, to $13.3 million for the nine months ended September 30, 2022. This increase was primarily attributable to an increase in third-party research and development costs of $4.1 million, an increase in personnel-related costs of $1.3 million and an increase in other research and development expense of $0.5 million.

General and Administrative

General and administrative expenses increased by $4.1 million, from $6.1 million for the nine months ended September 30, 2021, to $10.3 million for the nine months ended September 30, 2022. This increase was primarily attributable to an increase in personnel-related costs of $2.7 million, an increase in professional fees of $0.7 million and increase in other general and administrative costs of $0.7 million.

Acquired In-Process Research and Development

Acquired in-process research and development expense increased by $17.7 million, from $0 for the nine months ended September 30, 2021, to $17.7 million for the nine months ended September 30, 2022. This increase was due to one-time acquired in-process research and development expense as a result of the transactions under Arimoclomol Purchase Agreement.

Other Expenses

Other expenses increased by $16.4 million, from $16.4 million for the nine months ended September 30, 2021, to $22,000 for the nine months ended September 30, 2022. This period-to-period change was primarily attributable to a net loss on extinguishment of debt of $16.1 million during 2021 which did not recur in 2022 and a change in fair value adjustment related to derivative and warrant liability of $0.4 million.

Liquidity and Capital Resources

Sources of Liquidity

Through September 30, 2022, we have funded our research and development and operating activities primarily through the issuance of debt, private placements of redeemable convertible preferred stock and the sale of common stock in our initial public offering, at-the-market offering, underwritten public offerings, through our purchase agreements with Lincoln Park Capital LLC, or Lincoln Park, and from revenue received under the AZSTARYS License Agreement, the Corium Consulting Agreement and other consulting arrangements and the Arimoclomol EAP. As of September 30, 2022, we had cash, cash equivalents and investments of $107.4 million.

To date, we have generated revenue from the AZSTARYS License Agreement, reimbursement of out-of-pocket third-party costs, performance of consulting services and product sales under the Arimoclomol EAP.

In May 2022, we, through our newly formed wholly-owned subsidiary, KemPharm Denmark A/S, or KemPharm DK, entered into an Asset Purchase Agreement, or the Arimoclomol Purchase Agreement, with Orphazyme A/S in restructuring, a Danish public limited liability company, or Orphazyme. The transactions agreed to under the Arimoclomol Purchase Agreement closed on May 31, 2022. Under the terms of the Arimoclomol Purchase Agreement, KemPharm DK purchased all of the assets and operations of Orphazyme related to arimoclomol and settled all of Orphazyme’s actual outstanding liabilities to its creditors with a cash payment of $12.8 million. In addition, KemPharm DK agreed to assume an estimated reserve liability of $5.2 million related to revenue generated from Orphazyme’s Early Access Program in France.

In July 2020, we entered into the Corium Consulting Agreement under which Corium and Commave, respectively, engaged us to guide the product development and regulatory activities for certain current and potential future products in their portfolio, as well as continue supporting preparation for the potential commercial launch of AZSTARYS. Under the Corium Consulting Agreement, we were entitled to receive payments from Corium of up to $15.6 million, $13.6 million of which was earned in monthly installments through March 31, 2022, and paid in arrears. The remaining $2.0 million was conditioned upon the approval by the FDA of the NDA for Corium's product candidate, ADLARITY, which was approved in the first quarter of 2022. Corium also agreed to be responsible for and reimburse us for all development, commercialization and regulatory expenses incurred as part of the performance of the consulting services.

We have historically had minimal positive net cash flows from operations and we anticipate that we may continue to incur minimal positive net cash flows from operations for at least the next several years. We expect that our sources of revenue will be through payments arising from our license agreements with Commave and KVK, or through potential consulting arrangements, product sales under the Arimoclomol EAP and any other future arrangements related to one of our product candidates.

In January 2021, we completed the Public Offering. The aggregate gross proceeds to us from the Public Offering, including from the exercises by the underwriter of its over-allotment option, totaled $52.4 million, before deducting underwriting discounts and commissions and offering expenses payable by us. In January 2022, we filed an amendment to the registration statement on Form S-1 (File No. 333-250945) on Form S-3 covering the issuance of the shares of our common stock issuable upon the exercise of the warrants issued in the Public Offering and remaining unexercised as of the date of the amendment, which was declared effective on February 1, 2022.

In January 2021, we entered into the January 2021 Inducement Letters. We received aggregate gross proceeds of $44.0 million from the exercise of the Existing Warrants by the Exercising Holders and the sale of the January 2021 Inducement Warrants.

In April 2020, we received proceeds of $0.8 million from a loan, or the PPP Loan, under the Paycheck Protection Program, or the PPP, of the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, which we used to retain current employees, maintain payroll and make lease and utility payments. In May 2021, we received notice from the U.S. Small Business Administration that our PPP Loan was forgiven in full, including all principal and interest.

In June 2021, we entered into the June 2021 Inducement Letters. We received aggregate gross proceeds of $39.1 million for the exercise of the select January 2021 Inducement Warrants by the select warrant holders and the sale of the June 2021 Inducement Warrants.

In July 2021, we entered into the Equity Distribution Agreement with JMP and RBCCM under which we may offer and sell, from time to time at our sole discretion, shares of our common stock, having an aggregate offering price of up to $75.0 million through JMP and RBCCM as its sales agents. The issuance and sale, if any, of our common stock the Equity Distribution Agreement will be made pursuant to a registration statement on Form S-3. JMP and RBCCM may sell the common stock by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415 of the Securities Act of 1933, as amended. JMP and RBCCM will use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay JMP and RBCCM a commission equal to 3.0% in the aggregate of the gross sales proceeds of any common stock sold through JMP and RBCCM under the Equity Distribution Agreement. We filed a registration statement on Form S-3 covering the sale of the shares of our common stock up to $350.0 million, $75.0 million of which was allocated to the sales of the shares of common stock issuable under the Equity Distribution Agreement, which was declared effective on July 12, 2021. As of September 30, 2022, no shares have been issued or sold under the Equity Distribution Agreement.

Share Repurchase Program

On December 20, 2021, we initiated a share repurchase program, or the Share Repurchase Program, pursuant to which we may repurchase up to $50 million of shares of our common stock through December 31, 2023. Capital allocation to the Share Repurchase Program will be based on a variety of factors, including our business results, the receipt of royalties and sales milestones under the AZSTARYS License Agreement, and potentially other sources of non-dilutive capital that may become available to us. Repurchases will be made in compliance with Rule 10b-18 of the Securities Exchange Act of 1934, as amended, subject to a variety of factors, including the market price of our common stock, general market and economic conditions and applicable legal requirements. The exact number of shares to be repurchased by us is not guaranteed and the program may be suspended, modified, or discontinued at any time without prior notice. As of September 30, 2022, we have repurchased 909,953 shares of our common stock for approximately $7.5 million under the Share Repurchase Program.

Convertible Debt

As of September 30, 2022, we had no convertible notes outstanding. During the first quarter of 2021 we repaid in full the convertible notes and terminated the Deerfield Facility Agreement.

Deerfield Facility Agreement

In June 2014, we entered into the Deerfield Facility Agreement as a $60.0 million multi-tranche credit facility with Deerfield. At the time we entered into the Deerfield Facility Agreement, we borrowed the first tranche, which consisted of a $15.0 million term note and the $10.0 million convertible note, or the Deerfield Convertible Note.

The Deerfield Convertible Note originally bore interest at 9.75% per annum but was subsequently reduced to 6.75%. Interest accrued on the outstanding balance under the Deerfield Convertible Note was due quarterly in arrears. We originally had to repay one-third of the outstanding principal amount of the Deerfield Convertible Note on the fourth and fifth anniversaries of the Deerfield Facility Agreement (June 2018 and June 2019). In June 2018, Deerfield agreed to convert approximately $3.3 million of the principal amount then due, plus approximately $0.2 million of accrued interest, into 37,410 shares of our common stock. In September 2019, we entered into an amendment with Deerfield in order to (i) reduce the interest rate applicable under the Deerfield Facility Agreement from 9.75% to 6.75%, (ii) provide for “payment in kind” of interest on the Loans (as defined in the Deerfield Facility Agreement), and (iii) defer the Loan payments due pursuant to the Deerfield Facility Agreement until June 1, 2020. In December 2019, we entered into another amendment with Deerfield in order to (i) defer the Loan payments due pursuant to the Deerfield Facility Agreement until March 31, 2021, and (ii) allow for the entries of additional debt and debt holders under the Deerfield Facility Agreement (as discussed in more detail below).

Pursuant to the Deerfield Facility Agreement, we issued to Deerfield 1,923,077 shares of our Series D redeemable convertible preferred stock, or Series D Preferred, as consideration for the loans provided to us thereunder. Upon closing of our initial public offering, these shares of Series D Preferred reclassified into 256,410 shares of our common stock (effected for the 16-for-1 reverse stock split in December 2020, this became 16,025 shares of our common stock).

We also issued to Deerfield the Deerfield Warrant to purchase 14,423,076 shares of our Series D Preferred at an initial exercise price of $0.78 per share. Upon closing of our initial public offering, this warrant converted into a warrant exercisable for 1,923,077 shares of our common stock at an exercise price of $5.85 per share (effected for the 16-for-1 reverse stock split in December 2020, this became a warrant exercisable for 120,192 shares of our common stock at an exercise price of $93.60 per share). Upon the closing of the January 2021 Inducement Transaction, in accordance with the anti-dilution provisions contained within the Deerfield Warrant, the exercise price of the Deerfield Warrant was reduced to $46.25 per share. Further, upon closing of the June 2021 Inducement Transaction, in accordance with the anti-dilution provisions contained within the Deerfield Warrant, the exercise price of the Deerfield Warrant was reduced to $38.34 per share.

2021 Notes

In February 2016, we issued our 5.50% Senior Convertible Notes due 2021, or the 2021 Notes, in aggregate principal amount of $86.3 million. The 2021 Notes were originally issued to Cowen and Company and RBCCM LLC as representatives of the several initial purchasers, who subsequently resold the 2021 Notes to qualified institutional buyers in reliance on the exemption from registration provided by Rule 144A under the Securities Act.

The 2021 Notes were issued pursuant to an indenture, dated as of February 9, 2016, between us and U.S. Bank National Association, as trustee. Interest on the 2021 Notes was payable semi-annually in cash in arrears on February 1 and August 1 of each year, beginning on August 1, 2016, at a rate of 5.50% per year. The 2021 Notes matured on February 1, 2021, unless earlier converted or repurchased.

In multiple exchanges occurring in October 2018, December 2019 and January 2020, all outstanding 2021 Notes were exchanged by the holders thereof for either shares of our common stock or the December 2019 Notes and January 2020 Note issued under the terms of the Deerfield Facility Agreement.

2021 Note Exchange Effected in January 2020

In January 2020, we entered into a January 2020 Exchange Agreement, or the January 2020 Exchange Agreement, with M. Kingdon Offshore Master Fund, LP, or Kingdon. Under the January 2020 Exchange Agreement, we issued the January 2020 Note as a senior secured convertible note in the aggregate principal amount of approximately $3.0 million in exchange for the cancellation of an aggregate of approximately $3.0 million of principal amount and accrued interest of the 2021 Note then owned by Kingdon. Upon entering into the January 2020 Exchange Agreement, we agreed to pay Kingdon an interest payment of approximately $37,000, which represents 50% of the accrued and unpaid interest, as of January 13, 2020, on Kingdon's 2021 Note. The remainder of such interest was included in the principal amount of the January 2020 Note.

The January 2020 Note was issued with substantially the same terms and conditions as the December 2019 Notes (as amended by the amendment described in more detail below).

In connection with entering into the January 2020 Exchange Agreement, we entered into an Amendment to Facility Agreement and December 2019 Notes and Consent, or the December 2019 Note Amendment, with the December 2019 Holders that, among other things, (i) amended the December 2019 Notes to (a) reduce the Conversion Price (as defined in the December 2019 Notes) from $273.76 to $93.60 per share, (b) increased the Floor Price (as defined in the December 2019 Notes) from $6.08 to $9.328 per share, and (ii) amended Deerfield Facility Agreement to (x) provide for Kingdon to join the Deerfield Facility Agreement as a Lender (as defined in the Deerfield Facility Agreement) and (y) provide that the 2020 Note and shall constitute a "Senior Secured Convertible Note" (as defined in the Deerfield Facility Agreement) for purposes of the Deerfield Facility Agreement and other Transaction Documents (as defined in the Deerfield Facility Agreement). As a result of the December 2019 Note Amendment, the December 2019 Notes were convertible, by their terms, into an aggregate of 11,753,016 shares of our common stock, assuming a conversion date of January 13, 2020 (effected for the 16-for-1 reverse stock split in December 2020, this became 734,562 shares of our common stock).

Debt Restructuring

In December 2020, we entered into the December 2020 Exchange Agreement, which was amended on December 24, 2020. Pursuant to the December 2020 Exchange Agreement, (a) we made the Debt Payment as a cash pre-payment of a portion of principal amount of the Senior Secured Notes and the Deerfield Note to the Deerfield Lenders, DSC and Kingdon, or, collectively, the Holders, in an aggregate amount equal to approximately $30.3 million; and (b) we issued 31,476.98412 shares of our Series B-2 Preferred Stock and warrants exercisable for 3,632,019 shares of our common stock, or the Exchange Warrants, in exchange for the cancellation of a portion of the principal amount of the Senior Secured Notes and Deerfield Note owned by the Holders, with such transaction referred to as the Exchange. Immediately following the completion of the Exchange and Debt Payment, the aggregate balance of principal and accrued interest remaining outstanding under the Facility Notes was approximately $7.6 million.

The December 2020 Exchange Agreement amended the Senior Secured Notes to provide that the failure of our common stock to remain listed on an eligible securities market will not constitute a "Major Transaction" unless such failure occurs after March 31, 2023.

The December 2020 Exchange Agreement amended the Deerfield Facility Agreement in order to, among other things, (i) extend the maturity date of the Senior Secured Notes and the Deerfield Note to March 31, 2023, (ii) provide for cash payments of interest on the Loans (as defined in the Deerfield Facility Agreement) for the periods following July 1, 2021, and (iii) provide for specified prepayment terms on the Loans.

The December 2020 Exchange Agreement amended that certain Amended and Restated Investors' Rights Agreement, dated as of February 19, 2015, or the IRA, by and among us, Deerfield and the other parties signatory thereto in order to, among other things, add Deerfield Special Situations Fund, L.P. as a party thereto and to give effect to the issuance of the Exchange Warrants and our registration obligations under the December 2020 Exchange Agreement (as described in more detail below).

The Exercise Warrants are subject to substantially the same terms and conditions as the Existing Warrants, with an exercise price equal to the exercise price per share of the Existing Warrants and will provide that the Holders will be limited from exercising such Exchange Warrants if, as a result of such exercise, such holders (together with certain affiliates and "group" members of such holders) would beneficially own more than 4.985% of the total number of shares of our common stock then issued and outstanding.

Pursuant to the terms of the December 2020 Exchange Agreement, we also filed a registration statement to register for resale under the Securities Act the shares of common stock issuable upon conversion of the shares of Series B-2 Preferred Stock and exercise of the Exchange Warrants.

In connection with the December 2020 Exchange Agreement, we filed an Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Convertible Preferred Stock, or the Amended and Restated Series B-2 Certificate of Designation, with the Secretary of State of the State of Delaware, setting forth the preferences, rights and limitations of the Series B-2 Preferred Stock.

The shares of Series B-2 Preferred Stock were convertible into an aggregate of 4,842,690 shares of our common stock. Each share of Series B-2 Preferred Stock had an aggregate stated value of $1,000 and was convertible into shares of our common stock at a per share price equal to $6.4999 (subject to adjustment to reflect stock splits and similar events).

In March 2021, all shares of Series B-2 Preferred Stock converted into common stock.

In June 2021, we filed with the Secretary of State of the State of Delaware a Certificate of Elimination of Series B-2 Convertible Preferred Stock, eliminating from our Certificate of Incorporation the 31,480 shares designated as Series B-2 Convertible Preferred Stock.

December 2020 Exchange Agreement Amendment

On January 12, 2021, in connection with the transactions contemplated by the December 2020 Exchange Agreement, we entered into an Amendment to Senior Secured Convertible Notes and Amendment to Warrant, or the January 2021 Amendment, with the Deerfield Holders. The January 2021 Amendment modified certain specified terms of (i) the Facility Notes and (ii) the Deerfield Warrant to, among other things, exclude the transactions contemplated by the December 2020 Exchange Agreement and issuance of securities pursuant to the Underwriting Agreement from the anti-dilution provisions of the Facility Notes and the Deerfield Warrant.

Series B-2 Preferred Stock

On January 11, 2021, as a condition to the closing of the transactions contemplated by the December 2020 Exchange Agreement, we filed an Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Convertible Preferred Stock, or the Series B-2 Certificate of Designation, with the Secretary of State of the State of Delaware, setting forth the preferences, rights and limitations of the Series B-2 Preferred Stock.

Payoff of Facility Agreement Notes and Termination of Facility Agreement

On February 8, 2021, we entered into a payoff letter with the Facility Agreement Note Holders, pursuant to which we agreed to pay off and thereby terminate the Facility Agreement.

Pursuant to the payoff letter, we paid a total of $8.0 million to the Facility Agreement Note Holders, representing the principal balance, accrued interest outstanding and a prepayment fee in repayment of our outstanding obligations under the Facility Agreement.

Pursuant to the payoff letter, all outstanding indebtedness and obligations owed by us to the Facility Agreement Note Holders under the Facility Agreement have been paid in full. The Facility Agreement and the notes thereunder, as well as the security interests in the assets of us securing the Facility Agreement and note obligations, have been terminated. The Facility Agreement Note Holders will retain the warrants previously issued to them.

Line of Credit

In May 2022, we entered into a $20.0 million revolving loan agreement with Ameris Bank, as lender, or the Line of Credit. Proceeds of the revolving facility provided by the Line of Credit are to be used for general corporate purposes. Loans under the Line of Credit bear interest at the Secured Overnight Financing Rate ("SOFR") plus 1.60%, with a SOFR floor of 0.00%

The revolving facility under the Line of Credit is secured by a perfected security interest in deposit accounts. The revolving facility under the Line of Credit is subject to customary affirmative and negative covenants.

The latest maturity date of the loans under the Line of Credit is May 31, 2025. The Line of Credit contains customary events of default that could lead to an acceleration of the loans, including cross-default, bankruptcy and payment defaults. As of September 30, 2022, we have drawn $12.8 million from the Line of Credit to finance the transactions under the Arimoclomol Purchase Agreement, and this amount is supported by a $12.8 million certificate of deposit which is shown as long-term investments in the unaudited condensed consolidated balance sheets. The remaining $7.2 million available under the Line of Credit is secured by a separate interest-bearing certificate of deposit and is also recorded as long-term investments in the unaudited condensed consolidated balance sheets as of September 30, 2022. These certificates of deposit are pledged as collateral against the Line of Credit.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine months ended September 30,	
	2022	2021
Net cash (used in) provided by operating activities	$ (14,255)	$ 11,287
Net cash used in investing activities	(36,656)	(85)
Net cash provided by financing activities	8,609	115,979
Effect of exchange rate changes on cash and cash equivalents	15	—
Net (decrease) increase in cash and cash equivalents	$ (42,287)	$ 127,181

Operating Activities

For the nine months ended September 30, 2022, net cash used in operating activities of $14.3 million consisted of a net loss of $32.5 million and $3.9 million in changes in working capital, partially offset by $22.2 million in adjustments for non-cash items. Net loss was primarily attributable to our spending on research and development programs and operating costs, partially offset by revenue received under the AZSTARYS License Agreement, Arimoclomol EAP and the Corium Consulting Agreement. The changes in working capital consisted of $1.2 million related to a change in prepaid expenses and other assets, $4.6 million related to a change in accounts and other receivables, $0.2 million related to a change in operating lease liabilities and $0.4 million related to a change in other liabilities, partially offset by $1.3 million related to a change in accounts payable and accrued expenses, $0.3 million related to a change in inventories, $0.1 million related to a change in operating lease right-of-use assets and $0.9 million related to a change in discount and rebate liabilities. The adjustments for non-cash items primarily consisted of stock-based compensation expense of $3.3 million, a change in the fair value adjustment related to investments of $0.6 million, $17.7 million related to acquired in-process research and development which was expensed as part of the transactions under the Arimoclomol Purchase Agreement and $0.8 million related to depreciation, amortization and other items, partially offset by a change in the fair value adjustment related to derivative and warrant liabilities of $0.3 million.

For the nine months ended September 30, 2021, net cash provided by operating activities of $11.3 million consisted of $18.5 million in adjustments for non-cash items, partially offset by a net loss of $5.9 million and $1.3 million in changes in working capital. The adjustments for non-cash items primarily consisted of a loss on extinguishment of debt of $16.1 million, stock-based compensation expense of $1.6 million, amortization of debt issuance costs and debt discount of $0.2 million, a change in the fair value adjustment related to derivative and warrant liabilities of $0.1 million and $0.5 million related to depreciation, amortization and other items. Net loss was primarily attributable to a loss on extinguishment of debt and our spending on research and development programs and operating costs, partially offset by revenue received under the AZSTARYS License Agreement and the Corium Consulting Agreement. The changes in working capital consisted of $1.9 million related to a change in accounts payable and accrued expenses, $0.2 million related to a change in operating lease liabilities and $1.4 million related to a change in prepaid expenses and other assets, partially offset by $1.0 million related to a change in accounts and other receivables, $0.1 million related to a change in operating lease right-of-use assets and $1.1 million related to a change in other liabilities.

Investing Activities

For the nine months ended September 30, 2022, net cash used in investing activities was $36.7 million, which was attributable to net acquisition costs of the transactions under the Arimoclomol Purchase Agreement of $14.1 million and purchases of investments of $23.8 million, partially offset by maturities of investments of $1.3 million.

For the nine months ended September 30, 2021, net cash used in investing activities was $85,000, which was attributable to purchases of property and equipment.

Financing Activities

For the nine months ended September 30, 2022, net cash provided by financing activities was $8.6 million, which was primarily attributable to proceeds from the issuance of debt of $12.8 million, proceeds from insurance financing arrangements of $1.3 million and proceeds from sales of common stock under the Employee Stock Purchase Plan (the "ESPP") of $0.2 million, partially offset by payments to repurchase shares as part of the Share Repurchase Program of $4.7 million, payments of principal on insurance financing arrangements of $0.9 million and payment of offering costs of $0.1 million.

For the nine months ended September 30, 2021, net cash provided by financing activities was $116.0 million, which was primarily attributable to net proceeds from sales of our common stock under the Public Offering of $49.3 million, net proceeds from the January 2021 Inducement Transaction of $41.4 million, net proceeds from the June 2021 Inducement Transaction of $36.8 million and net proceeds from the exercise of common stock warrants of $30.8 million, partially offset by payment of offering costs of $1.3 million, repayment of principal on finance lease liabilities of $0.2 million, payment of debt issuance costs of $2.9 million and repayment of principal on convertible notes of $37.9 million.

Future Funding Requirements

Based on our current operating forecast, we believe that our existing cash, cash equivalents and investments will be sufficient to fund our operations into 2026. This estimate does not include our projected revenue, a portion of which is based on royalties from commercial sales and upon the achievement of milestones in the AZSTARYS License Agreement and the APADAZ License Agreement. Certain of the milestones are associated with regulatory matters that are outside our control.

Potential near-term sources of additional funding include:

- any revenues generated under either the AZSTARYS License Agreement or the APADAZ License Agreement;
- any consulting services revenue or short-term milestone payments generated under the AZSTARYS License Agreement;
- any product sales under the Arimoclomol EAP; and
- any consulting services revenue generated under potential consulting arrangements.

We cannot guarantee that we will be able to generate sufficient proceeds from any of these potential sources to fund our operating expenses.

To date, we have generated revenue from the AZSTARYS License Agreement, reimbursements of out-of-pocket third-party costs, the performance of consulting services and product sales under the Arimoclomol EAP. We expect that, for the foreseeable future, our only sources of revenues will be through payments arising from the AZSTARYS License Agreement, the APADAZ License Agreement, through potential consulting arrangements and any other future arrangements related to one of our product candidates and product sales under the Arimoclomol EAP. While we have entered into the APADAZ License Agreement to commercialize APADAZ in the United States, and entered into the AZSTARYS License Agreement to develop, manufacture and commercialize AZSTARYS and KP484, we cannot guarantee that this, or any strategy we adopt in the future, will be successful. For instance, we received milestone payments under the AZSTARYS License Agreement, but we cannot guarantee that we will earn any additional milestone or royalty payments under this agreement in the future. We also cannot guarantee that we will continue to generate revenue under the Arimoclomol EAP. We also expect to continue to incur additional costs associated with operating as a public company.

The COVID-19 pandemic has caused and continues to cause major disruptions to businesses and markets worldwide. We cannot predict what the long-term effects of this pandemic and the resulting economic disruptions may have on our liquidity and results of operations. The extent of the effect of the COVID-19 pandemic on our liquidity and results of operations will depend on a number of future developments, including the duration, spread and intensity of the pandemic, and governmental, regulatory and private sector responses, all of which are uncertain and difficult to predict. The COVID-19 pandemic may make it more difficult for us to enroll patients in any future clinical trials or cause delays in the regulatory approval of our product candidates. A portion of our projected revenue is based upon the achievement of milestones in the AZSTARYS License Agreement associated with regulatory matters that may be impacted by the COVID-19 pandemic. As a result, we cannot predict what, if any, impact that the COVID-19 pandemic may have on our ability to achieve these milestones. The economic uncertainty surrounding the COVID-19 pandemic and as a result of rising inflation and interest rates may also dramatically reduce our ability to secure debt or equity financing necessary to support our operations. We are unable to currently estimate the financial effect of the pandemic. If the pandemic continues to be a severe worldwide crisis, it could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

We have based our estimates of our cash needs and cash runway on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect and we cannot guarantee that we will be able to generate sufficient proceeds from the AZSTARYS License Agreement, the APADAZ License Agreement, the Corium Consulting Agreement, product sales under the Arimoclomol EAP and other potential consulting arrangements or other funding transactions to fund our operating expenses. To meet any additional cash requirements, we may seek to sell additional equity or convertible securities that may result in dilution to our stockholders, issue additional debt or seek other third-party funding, including potential strategic transactions, such as licensing or collaboration arrangements. Because of the numerous risks and uncertainties associated with the development and commercialization of product candidates and products, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the commercialization and development of our partnered product or product candidates, should they obtain regulatory approval.

Critical Accounting Policies and Significant Judgments and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of our unaudited condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our unaudited condensed consolidated financial statements, as well as the reported revenues and expenses during the reported periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value 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 have not changed materially from those described in *Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations* of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 31, 2022.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our 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. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and our chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2022. Based on the evaluation of our disclosure controls and procedures as of September 30, 2022, our chief executive officer and our chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during our fiscal quarter ended September 30, 2022, that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may be involved in routine legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of our business. We believe there is no litigation pending that would reasonably be expected to, individually or in the aggregate, have a material adverse effect on our results of operations or financial condition.

ITEM 1A. RISK FACTORS

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider all the risk factors and uncertainties described in Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 31, 2022, before investing in our common stock. Except as disclosed below, there have been no material changes to the risk factors described in that report. If any of those risks materialize, our business, financial condition and results of operations could be seriously harmed. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements because of those risk factors and the other factors described in in this Quarterly Report on Form 10-Q.

If we engage in acquisitions to grow our business, we will incur a variety of costs and may potentially face numerous risks that could adversely affect our business and operations and cause our stock price to decline.

If appropriate opportunities become available, we may seek to acquire businesses or assets to enhance our business. For example, in May 2022, we acquired all of the assets and operations of Orphazyme related to arimoclomol. In connection with any acquisitions, we could issue additional equity securities, which would dilute our stockholders, incur substantial debt to fund the acquisitions or assume significant liabilities.

Acquisitions involve many and diverse risks and uncertainties, including problems integrating the purchased operations or assets as well as unanticipated costs, liabilities, and economic, political, legal and regulatory challenges due to our inexperience operating in new regions or countries, and we may fail to successfully integrate acquired companies, such as Orphazyme, or retain key personnel from the acquired company. To date, we have limited experience with acquisitions and the integration of acquired operations and personnel. Acquisitions may divert our attention from our core business. Acquisitions may require us to record goodwill and non-amortizable intangible assets that will be subject to testing on a regular basis and potential period impairment charges, incur amortization expenses related to certain intangible assets, and incur write offs and restructuring and other related expenses, any of which could harm our operating results and financial condition.

New business strategies, especially those involving acquisitions, are inherently risky and may not be successful. Failure to successfully identify, complete, manage and integrate acquisitions could materially and adversely affect our business, financial condition and results of operations and could cause our stock price to decline.

Global economic uncertainty and other global economic or political and regulatory developments could have a material adverse effect on our business, cash flows, financial condition and/or prospects.

Growth in the global pharmaceutical market has become increasingly tied to (i) global economic growth as an economic downturn may, for example as a result of the COVID-19 pandemic's paralyzing effects on economic activities, reduce the amount of funding for the pharmaceutical sector as a whole or certain diseases targeted by us and (ii) political conditions, tension and uncertainty which could, for instance, impact the regulations applicable to us.

Uncertain political and geopolitical conditions currently exist in various parts of the world. At the end of 2021 and into 2022, tensions between the United States and Russia escalated when Russia amassed large numbers of military ground forces and support personnel on the Ukraine-Russia border and in February 2022, Russia launched a wide-ranging attack on Ukraine. In response, the North Atlantic Treaty Organization ("NATO") has deployed additional military forces to Eastern Europe, and the United Kingdom, the European Union and the United States announced certain sanctions against Russia. The conflict in Ukraine and any retaliatory measures taken by the United States and NATO could threaten global security and result in further regional conflict and otherwise have a lasting impact on regional and global economies, any or all of which could adversely affect our business. In addition, the full effects of the United Kingdom’s exit from the EU in January 2020 are impossible to predict but may result in significant market volatility and dislocation, and adversely affect the United Kingdom, European and global economy.

Future legal or regulatory changes in jurisdictions where we currently operate, or in such jurisdictions in which we may choose to operate in the future, could materially and adversely affect our business, results of operations, cash flows, financial condition and/or prospects, including by imposing regulatory and operational restrictions and compliance obligations on our business, reducing our revenue or increasing our expenses.

The above circumstances, individually or in the aggregate, could have a material adverse effect on our business, cash flows, financial condition and/or prospects.

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

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities By the Issuer and Affiliated Purchasers

Issuer Purchases of Equity Securities

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs(1)	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs
July 1, 2022 through July 31, 2022	—	$ —	—	$ 42,500,000
August 1, 2022 through August 31, 2022	—	—	—	42,500,000
September 1, 2022 through September 30, 2022	—	—	—	42,500,000
Total	**—**	**$ —**	—	**$ 42,500,000**

(1) On December 20, 2021, the Company announced that it had initiated a share repurchase program, or the Share Repurchase Program, pursuant to which the Company may repurchase up to $50 million of shares of its common stock through December 31, 2023. Repurchases will be made in compliance with Rule 10b-18 of the Securities Exchange Act of 1934, as amended, subject to a variety of factors, including the market price of the Company's common stock, general market and economic conditions and applicable legal requirements. The exact number of shares to be repurchased by the Company is not guaranteed and the program may be suspended, modified, or discontinued at any time without prior notice.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The following is a list of exhibits filed as part of this Form 10-Q (the SEC file number for all items incorporated by reference herein from reports on Forms 10-K, 10-Q, and 8-K is 001-36913):

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of KemPharm, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on April 21, 2015).
3.1.1	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant, effective as of December 23, 2020 (incorporated herein by reference to Registrant's Current Report on Form 8-K as filed with the SEC on December 23, 2020).
3.2	Amended and Restated Bylaws, as currently in effect, of KemPharm, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on July 17, 2020).
4.1	Specimen stock certificate evidencing shares of Common Stock (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 12, 2021).
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1**	Certification of the Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18. U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of the Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18. U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104**	Cover page Interactive Data File (embedded within the Inline XBRL and combined in Exhibit 101)

* Filed herewith
** Furnished herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KemPharm, Inc.

Date: November 9, 2022

By: /s/ Travis C. Mickle
Travis C. Mickle, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2022

By: /s/ R. LaDuane Clifton
R. LaDuane Clifton, CPA
Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)

EXHIBIT 31.1

CERTIFICATION

I, Travis C. Mickle, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of KemPharm, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer 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.

November 9, 2022

/s/ Travis C. Mickle

Name: Travis C. Mickle, Ph.D.

Title: President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, R. LaDuane Clifton, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of KemPharm, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer 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.

November 9, 2022

/s/ R. LaDuane Clifton

Name: R. LaDuane Clifton, CPA

Title: Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of KemPharm, Inc., (the "Company") for the quarterly period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Travis C. Mickle, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 9, 2022

/s/ Travis C. Mickle

Name: Travis C. Mickle, Ph.D.

Title: President and Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, is not being "filed" by the Company as part of the Report or as a separate disclosure document and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

EXHIBIT 32.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of KemPharm, Inc., (the "Company") for the quarterly period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, R. LaDuane Clifton, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 9, 2022

/s/ R. LaDuane Clifton
Name: R. LaDuane Clifton, CPA
Title: Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, is not being "filed" by the Company as part of the Report or as a separate disclosure document and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.