

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, DC 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 Number: 001-38276

APELLIS PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

100 Fifth Avenue,
Waltham, MA
(Address of principal executive offices)

27-1537290
(I.R.S. Employer
Identification No.)

02451
(Zip Code)

Registrant's telephone number, including area code: (617) 977-5700

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of November 1, 2022, the registrant had 110,575,547 shares of common stock, \$0.0001 par value per share, outstanding.

APELLIS PHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2022

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Special Note Regarding Forward-Looking Statements and Industry Data

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our plans with respect to our ongoing and planned clinical trials for our product candidates, whether conducted by us or Swedish Orphan Biovitrum AB (Publ), or Sobi, or by any future collaborators, including the timing of dosing of patients, enrollment and completion of these trials and of the anticipated results from these trials;
- the ongoing commercialization of EMPAVELI and our preparation for the commercialization of intravitreal pegcetacoplan;
- our sales, marketing and distribution capabilities and strategies, including for the commercialization and manufacturing of EMPAVELI, intravitreal pegcetacoplan and any future products;
- the rate and degree of market acceptance and clinical utility of EMPAVELI, intravitreal pegcetacoplan and any future products;
- our plans to develop our current and future product candidates for any additional indications;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- our plans to initiate clinical trials of our current and future product candidates;
- the potential clinical benefits and attributes of our current and future product candidates we may develop and the inhibition of C3;
- our plans to research and develop any current and future product candidates we may develop;
- our current and any future collaborations for the development and commercialization of our current and future product candidates;
- the potential benefits of any collaboration;
- the rate and degree of market acceptance and clinical utility of any products for which we receive marketing approval;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our ability to identify additional products or product candidates with significant commercial potential;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- developments relating to our competitors and our industry;
- the impact of the COVID-19 pandemic on our clinical trials, business and operations; and
- the impact of new government laws and regulations (including tax).

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, particularly in the “Risk Factors” section, that 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, collaborations, joint ventures or investments that we may make or enter into.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed or incorporated by reference as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

This Quarterly Report on Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. All of the market data used in this Quarterly Report on Form 10-Q involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. We believe that the information from these industry publications, surveys and studies is reliable. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section titled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021 and in this Quarterly Report on Form 10-Q. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us. The Apellis, EMPAVELI and Apellis Assist names and logos are our trademarks, trade names and service marks. The other trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

Note regarding certain references in this Quarterly Report on Form 10-Q

Unless otherwise stated or the context indicates otherwise, all references herein to “Apellis,” “Apellis Pharmaceuticals, Inc.,” “we,” “us,” “our,” “our company,” “the Company” and similar references refer to Apellis Pharmaceuticals, Inc. and its wholly owned subsidiaries.

In addition, unless otherwise stated or the context indicates otherwise, all references in this Quarterly Report on Form 10-Q to “EMPAVELI (pegcetacoplan)” and “EMPAVELI” refer to pegcetacoplan in the context of the commercially available product for which we received approval from the United States Food and Drug Administration in May 2021 for the treatment of adults with paroxysmal nocturnal hemoglobinuria, or PNH, and references to Aspaveli refer to pegcetacoplan in the context of the commercially available product for which Sobi and us received approval from the European Commission in December 2021 for the treatment of adults with PNH who are anemic after treatment with a C5 inhibitor for at least three months, in each case, as more fully described herein; whereas, unless otherwise stated or the context indicates otherwise, all references herein to “pegcetacoplan” refer to pegcetacoplan in the context of the product candidate for which we are exploring further applications and indications, as more fully described herein. The other trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

PART I—FINANCIAL INFORMATION**Item 1. Financial Statements.**

APELLIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except per share amounts)

	September 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 584,189	\$ 640,192
Marketable securities	124,364	60,358
Accounts receivable	8,091	10,103
Inventory	59,753	16,286
Prepaid assets	30,356	24,868
Restricted cash	1,259	1,563
Other current assets	23,925	70,677
Total current assets	<u>831,937</u>	<u>824,047</u>
Non-current assets:		
Right-of-use assets	19,522	19,901
Property and equipment, net	5,681	6,177
Other assets	15,752	31,640
Total assets	<u>\$ 872,892</u>	<u>\$ 881,765</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 14,099	\$ 16,909
Accrued expenses	79,778	103,239
Current portion of development liability	16,146	7,584
Current portion of right-of-use liabilities	5,423	4,115
Total current liabilities	<u>115,446</u>	<u>131,847</u>
Long-term liabilities:		
Long-term development liability	340,142	345,151
Convertible senior notes	92,663	189,024
Right-of-use liabilities	15,287	17,081
Other liabilities	1,938	—
Total liabilities	<u>565,476</u>	<u>683,103</u>
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000 shares authorized, and zero shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, \$0.0001 par value; 200,000 shares authorized at September 30, 2022 and December 31, 2021; 110,476 shares issued and outstanding at September 30, 2022, and 97,524 shares issued and outstanding at December 31, 2021	11	10
Additional paid-in capital	2,453,301	1,857,430
Accumulated other comprehensive loss	(3,027)	(2,090)
Accumulated deficit	(2,142,869)	(1,656,688)
Total stockholders' equity	<u>307,416</u>	<u>198,662</u>
Total liabilities and stockholders' equity	<u>\$ 872,892</u>	<u>\$ 881,765</u>

See accompanying notes to unaudited condensed consolidated financial statements

APELLIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME/(LOSS)
(Unaudited)
(Amounts in thousands, except per share amounts)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue:				
Product revenue, net	\$ 17,676	\$ 5,314	\$ 45,439	\$ 5,937
Licensing and other revenue	4,380	336	7,320	336
Total revenue:	22,056	5,650	52,759	6,273
Operating expenses:				
Cost of sales	1,381	149	2,711	149
Research and development	95,207	87,733	287,813	267,688
Cost of research collaboration	—	—	—	50,000
General and administrative	78,406	45,763	192,795	135,309
Total operating expenses:	174,994	133,645	483,319	453,146
Net operating loss	(152,938)	(127,995)	(430,560)	(446,873)
Loss on conversion of debt	(32,890)	(61,102)	(32,890)	(100,589)
Loss from remeasurement of development derivative liability	—	(4,219)	—	(42,483)
Interest income	2,809	144	4,339	381
Interest expense	(7,903)	(2,282)	(24,888)	(10,223)
Other income/(expense), net	99	(117)	(42)	1,366
Net loss before taxes	(190,823)	(195,571)	(484,041)	(598,421)
Income tax expense	446	—	2,140	—
Net loss	\$ (191,269)	\$ (195,571)	\$ (486,181)	\$ (598,421)
Other comprehensive gain/(loss):				
Unrealized gain/(loss) on marketable securities	435	(25)	(383)	19
Foreign currency loss	(268)	(156)	(554)	(1,912)
Total other comprehensive income/(loss)	167	(181)	(937)	(1,893)
Comprehensive loss, net of tax	\$ (191,102)	\$ (195,752)	\$ (487,118)	\$ (600,314)
Net loss per common share, basic and diluted	\$ (1.75)	\$ (2.28)	\$ (4.65)	\$ (7.31)
Weighted-average number of common shares used in net loss per common share, basic and diluted	109,126	85,661	104,608	81,846

See accompanying notes to unaudited condensed consolidated financial statements

APELLIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)
(Amounts in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income/(Loss)	Accumulated Deficit	Total Stockholders' Equity
	Outstanding Shares	Amount				
Balance at January 1, 2022	97,524	\$ 10	\$ 1,857,430	\$ (2,090)	\$ (1,656,688)	\$ 198,662
Common Stock -follow-on-offering	8,564	1	380,119	—	—	380,120
Issuance of common stock upon exercise of stock options	239	—	4,000	—	—	4,000
Vesting of restricted stock units, net of shares withheld for taxes	113	—	(2,416)	—	—	(2,416)
Share-based compensation expense	—	—	20,773	—	—	20,773
Unrealized gain on available-for-sale investments	—	—	—	(52)	—	(52)
Net loss	—	—	—	—	(138,935)	(138,935)
Foreign currency gain	—	—	—	83	—	83
Balance at March 31, 2022	106,440	11	2,259,906	(2,059)	(1,795,623)	462,235
Issuance of common stock upon exercise of stock options	283	—	4,770	—	—	4,770
Vesting of restricted stock units, net of shares withheld for taxes	26	—	(536)	—	—	(536)
Share-based compensation expense	—	—	22,530	—	—	22,530
Issuance of common stock to employee stock purchase plan	92	—	2,531	—	—	2,531
Unrealized loss on available-for-sale investments	—	—	—	(766)	—	(766)
Net loss	—	—	—	—	(155,977)	(155,977)
Foreign currency loss	—	—	—	(369)	—	(369)
Balance at June 30, 2022	106,841	\$ 11	\$ 2,289,201	\$ (3,194)	\$ (1,951,600)	\$ 334,418
Issuance of shares in exchange of Convertible Notes, including issuance costs	3,073	—	129,636	—	—	129,636
Forfeiture of accrued interest in exchange of Convertible Notes	—	—	1,287	—	—	1,287
Issuance of common stock upon exercise of stock options	521	—	10,639	—	—	10,639
Vesting of restricted stock units, net of shares withheld for taxes	41	—	(1,003)	—	—	(1,003)
Share-based compensation expense	—	—	23,541	—	—	23,541
Issuance of common stock to employee stock purchase plan	—	—	—	—	—	—
Unrealized gain on available-for-sale investments	—	—	—	435	—	435
Net loss	—	—	—	—	(191,269)	(191,269)
Foreign currency loss	—	—	—	(268)	—	(268)
Balance at September 30, 2022	110,476	\$ 11	\$ 2,453,301	\$ (3,027)	\$ (2,142,869)	\$ 307,416

See accompanying notes to unaudited condensed consolidated financial statements

APELLIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Continued from previous page)
(Unaudited)

(Amounts in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Outstanding Shares	Amount				
Balance at January 1, 2021	76,130	\$ 8	\$ 1,131,013	\$ (117)	\$ (926,347)	\$ 204,557
Impact of adoption of ASU 2020-06	—	—	(165,747)	—	16,013	(149,734)
Issuance of shares in exchange of 2019 Convertible Notes, including issuance costs	3,976	—	162,258	—	—	162,258
Forfeiture of accrued interest in exchange of 2019 Convertible Notes	—	—	1,668	—	—	1,668
Issuance of common stock upon exercise of stock options	285	—	2,588	—	—	2,588
Vesting of restricted stock units, net of shares withheld for taxes	47	—	(956)	—	—	(956)
Share-based compensation expense	—	—	16,439	—	—	16,439
Unrealized gain on available-for-sale investments	—	—	—	79	—	79
Net loss	—	—	—	—	(183,659)	(183,659)
Foreign currency loss	—	—	—	(1,582)	—	(1,582)
Balance at March 31, 2021	80,438	8	1,147,263	(1,620)	(1,093,993)	51,658
Issuance of common stock upon exercise of stock options	444	—	7,062	—	—	7,062
Vesting of restricted stock units, net of shares withheld for taxes	11	—	(233)	—	—	(233)
Share-based compensation expense	—	—	17,722	—	—	17,722
Issuance of common stock to employee stock purchase plan	63	—	1,698	—	—	1,698
Unrealized loss on available-for-sale investments	—	—	—	(35)	—	(35)
Net loss	—	—	—	—	(219,191)	(219,191)
Foreign currency loss	—	—	—	(174)	—	(174)
Balance at June 30, 2021	80,956	8	1,173,512	(1,829)	(1,313,184)	(141,493)
Issuance of shares in exchange of Convertible Notes, including issuance costs	6,071	1	258,104	—	—	258,105
Forfeiture of accrued interest in exchange of Convertible Notes	—	—	2,503	—	—	2,503
Issuance of common stock upon exercise of stock options	177	—	2,480	—	—	2,480
Vesting of restricted stock units, net of shares withheld for taxes	15	—	(362)	—	—	(362)
Share-based compensation expense	—	—	17,194	—	—	17,194
Unrealized loss on available-for-sale investments	—	—	—	(25)	—	(25)
Net loss	—	—	—	—	(195,571)	(195,571)
Foreign currency loss	—	—	—	(156)	—	(156)
Balance at September 30, 2021	87,219	9	1,453,431	(2,010)	(1,508,755)	(57,325)

See accompanying notes to unaudited condensed consolidated financial statements

APELLIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(Amounts in thousands)

	For the Nine Months Ended September 30,	
	2022	2021
Operating Activities		
Net loss	\$ (486,181)	\$ (598,421)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	66,844	51,355
Loss on conversion of debt	32,890	100,589
Loss from remeasurement of development derivative liability	—	42,483
Forfeiture of accrued interest in exchange of convertible notes	1,287	4,171
Amortization of right-of-use assets	(105)	110
Depreciation expense	1,164	1,006
Amortization of discounts for convertible notes, net of financing costs	386	821
Accretion of discount to development liability	20,053	—
Other liabilities	1,938	—
Changes in operating assets and liabilities:		
Accounts receivable	2,010	(2,618)
Inventory	(43,436)	(1,677)
Prepaid assets	(5,492)	(5,862)
Other current assets	45,457	6,677
Other assets	15,885	(3,956)
Accounts payable	(4,437)	(3,213)
Accrued expenses	(21,264)	(42,092)
Net cash used in operating activities	(373,001)	(450,627)
Investing Activities		
Purchase of property and equipment	(673)	(1,084)
Purchase of available-for-sale securities	(331,863)	(171,280)
Proceeds from maturity of available-for-sale securities	268,300	335,000
Net cash (used in) provided by investing activities	(64,236)	162,636
Financing Activities		
Proceeds from issuance of common stock, net of issuance costs	380,120	—
Payments for development derivative liability	—	(4,000)
Payments for development liability	(16,500)	—
Proceeds from exercise of stock options	19,409	12,131
Proceeds from issuance of common stock under employee share purchase plan	2,531	1,698
Payments of employee tax withholding related to equity-based compensation	(3,955)	(1,551)
Net cash provided by financing activities	381,605	8,278
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(675)	(2,024)
Net decrease in cash, cash equivalents and restricted cash	(56,307)	(281,737)
Cash, cash equivalents and restricted cash at beginning of period	641,755	567,045
Cash, cash equivalents and restricted cash at end of period	\$ 585,448	\$ 285,308
Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets:		
Cash and cash equivalents	\$ 584,189	\$ 283,745
Restricted cash	1,259	1,563
Total cash, cash equivalents, and restricted cash	\$ 585,448	\$ 285,308
Supplemental Disclosures		
Cash paid for interest	\$ 5,003	\$ 10,265
Cash paid for income taxes	\$ 156	\$ —
Convertible Notes exchanged for common stock	\$ 98,086	\$ 327,276

See accompanying notes to unaudited condensed consolidated financial statements

APELLIS PHARMACEUTICALS, INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Nature of Organization and Operations

Apellis Pharmaceuticals, Inc. (the “Company”) is a commercial-stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutic compounds to treat diseases with high unmet needs through the inhibition of the complement system, which is an integral component of the immune system, at the level of C3, the central protein in the complement cascade.

The Company was incorporated in September 2009 under the laws of the State of Delaware. The Company’s principal executive offices are located in Waltham, Massachusetts.

The Company’s operations since inception have been limited to organizing and staffing the Company, acquiring rights to product candidates, business planning, raising capital, developing its product candidates, and commercializing EMPAVELI (pegcetacoplan) for the treatment of paroxysmal nocturnal hemoglobinuria (“PNH”).

The Company is subject to risks common in the biotechnology industry including, but not limited to, raising additional capital, development by its competitors of new technological innovations, its ability to successfully complete preclinical and clinical development of product candidates and receive timely regulatory approval of products, market acceptance of the Company’s products, protection of proprietary technology, healthcare cost containment initiatives, and compliance with governmental regulations, including those of the U.S. Food and Drug Administration (“FDA”).

Liquidity and Going Concern

The accompanying unaudited condensed consolidated financial statements have been prepared on the basis of the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. As of November 7, 2022, the date of issuance of these unaudited condensed consolidated financial statements, the Company believes that its cash and cash equivalents and marketable securities of \$708.6 million as of September 30, 2022 will be sufficient to fund its operations and capital expenditures for at least the next twelve months. The Company’s future viability beyond that point is dependent on its ability to raise additional capital to finance its operations.

There are uncertainties associated with the Company’s ability to (1) obtain additional debt or equity financing on terms that are favorable to the Company, (2) enter into collaborative agreements with strategic partners, and (3) succeed in its future operations. If the Company is not able to obtain the required funding for its operations or is not able to obtain funding on terms that are favorable to the Company, it could be forced to delay, reduce or eliminate its research and development programs or future commercialization efforts and its business could be materially harmed.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) and following the requirements of the Securities and Exchange Commission (the “SEC”), for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP have been condensed or omitted and, accordingly, the consolidated balance sheet as of December 31, 2021 has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements. These financial statements have been prepared on the same basis as the Company’s annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair presentation of the Company’s financial information. The results of operations for the three and nine months ended September 30, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022 or for any other interim period or for any other future year.

The accompanying unaudited condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2021 included in the Company's Annual Report on Form 10-K filed with the SEC on February 28, 2022 (the "2021 Form 10-K").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: development derivative liability, accrued expenses, prepaid expenses, convertible debt and taxes.

Summary of Significant Accounting Policies

Reference is made to Note 2 Summary of Significant Accounting Policies in our 2021 Form 10-K for a detailed description of significant accounting policies. There have been no significant changes to our accounting policies as disclosed in our 2021 Form 10-K.

3. Product Revenues, Accounts Receivable, and Reserves for Product Sales

The Company received FDA approval for the sale of EMPAVELI in the United States in May 2021. The Company's product revenues, net of sales discounts and allowances and reserves, for the three months ended September 30, 2022 and 2021 were \$17.7 million and \$5.3 million, respectively. The Company's product revenues, net of sales discounts and allowances and reserves, for the nine months ended September 30, 2022 and 2021 were \$45.4 million and \$5.9 million, respectively.

The Company's accounts receivable balance of \$8.1 million as of September 30, 2022 and \$10.1 million as of December 31, 2021, consisted of EMPAVELI product sales receivable, net of discounts and allowances of \$0.3 million and \$0.2 million, respectively. The Company does not have a reserve against its receivable balance.

The Company's product sales reserves totaled \$2.0 million and \$1.0 million as of September 30, 2022 and December 31, 2021, respectively. These amounts are included in accrued expenses on the Company's unaudited condensed consolidated balance sheet.

4. Inventory

The Company's inventory of EMPAVELI consisted of the following as of September 30, 2022, and December 31, 2021 (in thousands):

	<u>September 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Raw materials	\$ 25,955	\$ 5,749
Semi-finished goods	33,124	10,058
Finished goods	674	479
Total Inventories	<u>\$ 59,753</u>	<u>\$ 16,286</u>

5. Prepaid Assets and Accrued Expenses

Prepaid assets include \$16.0 million and \$12.0 million of prepaid research and development costs as of September 30, 2022 and December 31, 2021, respectively.

Accrued expenses are as follows (in thousands):

	<u>September 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Accrued research and development	\$ 28,071	\$ 35,217
Accrued cost of research collaboration	—	25,000
Accrued license fee	—	5,000
Accrued royalties	723	—
Accrued payroll liabilities	33,467	25,212
Other	17,517	12,810
Total	<u>\$ 79,778</u>	<u>\$ 103,239</u>

6. Development Liability and Development Derivative Liability

On February 28, 2019, the Company entered into a development funding agreement (the “SFJ agreement”), with SFJ Pharmaceuticals Group (“SFJ”), under which SFJ agreed to provide funding to the Company to support the development of pegcetacoplan for the treatment of patients with PNH. Pursuant to the SFJ agreement, SFJ paid the Company \$60.0 million following the signing of the agreement and agreed to pay the Company up to an additional \$60.0 million in the aggregate in three equal installments upon the achievement of specified development milestones with respect to the Company’s Phase 3 program for pegcetacoplan in PNH.

On June 7, 2019, the Company and SFJ amended the development funding agreement, (the “SFJ amendment”). Under the SFJ amendment, SFJ agreed to make an additional \$20.0 million funding payment to the Company to support the development of systemic pegcetacoplan for the treatment of patients with PNH.

As of January 29, 2020, the Company had received a total of \$140.0 million from SFJ as the Company met milestones as identified in the SFJ agreement. The Company did not receive any additional funds from SFJ after January 29, 2020.

Under the SFJ agreement, following regulatory approval by the FDA for the use of systemic pegcetacoplan as a treatment for PNH, the Company is obligated to pay SFJ an initial payment of \$4.0 million and then an additional \$226.0 million in the aggregate in six additional annual payments with the majority of the payments being made from the third anniversary to the sixth anniversary of regulatory approval. The Company obtained regulatory approval by the FDA on May 14, 2021 and paid to SFJ the initial payment of \$4.0 million in June 2021 and the first annual payment of \$11.5 million in May 2022. The subsequent annual payments remaining are due and payable in May of each year from 2023 through 2027.

Under the SFJ agreement, following regulatory approval by the European Medicines Agency (the “EMA”) for the use of systemic pegcetacoplan as a treatment for PNH, the Company is obligated to pay SFJ an initial payment of \$5.0 million and then an additional \$225.0 million in the aggregate in six additional annual payments with the majority of the payments being made from the third anniversary to the sixth anniversary of regulatory approval. The Company obtained regulatory approval by the EMA on December 15, 2021 and paid to SFJ the initial payment of \$5.0 million in January 2022. The subsequent annual payments are due and payable in December of each year from 2022 through 2027.

Additionally, the Company granted a security interest to SFJ in all of its assets, excluding intellectual property and license agreements to which it is a party. In connection with the grant of the security interest, the Company agreed to certain affirmative and negative covenants, including restrictions on its ability to pay dividends, incur additional debt or enter into licensing transactions with respect to its intellectual property, other than specified types of licenses.

Prior to EMA approval on December 15, 2021, the SFJ agreement was presented as a derivative liability on the consolidated balance sheet and, as such, was recorded at fair value and remeasured each quarter. As the variability of the future payments derived from the underlying contingency (i.e., EMA approval and FDA approval) no longer exists, the Company remeasured the development derivative liability on December 15, 2021 and reclassified it from a development derivative liability to a development liability, with subsequent accounting to follow an effective interest accretion schedule to the fixed payment amounts.

From December 15, 2021 to the final annual payment due in December 2027, the development liability will be accreted from its initial carrying amount to the total payment amount using the effective interest rate method under FASB ASC Topic 835, *Interest*, over the remaining life of the SFJ agreement. The difference between the carrying amount and the total payment amount is presented as a discount to the development liability. The accretion is recorded as interest expense in the unaudited condensed consolidated statement of operations.

The following table summarizes the development liability (in thousands):

	September 30, 2022	December 31, 2021	Effective Interest Rate
Development liability	\$ 439,500	\$ 456,000	7.91 %
Less: Unamortized discount to development liability	(83,212)	(103,265)	
Less: Current portion of development liability, net of discount	(16,146)	(7,584)	
Total long term development liability	\$ 340,142	\$ 345,151	

For the three and nine months ended September 30, 2022, interest expense of \$6.7 million and \$20.1 million, respectively, was recorded for the accretion of the development liability.

The following table presents a rollforward of the development derivative liability for the nine months ended September 30, 2021 (in thousands):

Balance at fair market value, January 1, 2021	\$ 257,868
Loss from remeasurement of development derivative liability	17,084
Balance at fair market value, March 31, 2021	\$ 274,952
Amount repaid under the SFJ agreement and SFJ amendment	(4,000)
Loss from remeasurement of development derivative liability	21,180
Balance at fair market value, June 30, 2021	\$ 292,132
Amount repaid under the SFJ agreement and SFJ amendment	—
Loss from remeasurement of development derivative liability	4,219
Balance at fair market value, September 30, 2021	\$ 296,351

For the nine months ended September 30, 2021, the total change in fair value of \$42.5 million was recorded in loss from remeasurement of development derivative liability in the unaudited condensed consolidated statement of operations.

The derivative fair value as of September 30, 2021 was a Level 3 fair value measurement and was valued using a scenario-based discounted cash flow method, whereby each scenario made assumptions about the probability and timing of cash flows, and such cash flows are present valued using a risk-adjusted discount rate. The analysis is calibrated such that the value of the derivative as of the date of the SFJ agreement was consistent with an arm's-length transaction. Key inputs to the Level 3 fair value model included (i) the probability and timing of achieving stated development milestones to receive the next tranches of funding, (ii) the probability and timing of achieving FDA and EMA approval, (iii) SFJ's cost of borrowing (8.0%), and (iv) the Company's cost of borrowing (11.9%).

SFJ's implied cost of borrowing was 8.0% and the Company's implied cost of borrowing was 11.9% as of September 30, 2021. These implied costs of borrowing were determined assuming the SFJ agreement was initially executed with arm's-length terms. If the SFJ agreement was instead not determined to be an arm's-length transaction, then implied discount rates could differ.

7. Long-term Debt

Convertible Senior Notes

On September 16, 2019, the Company completed a private offering of convertible notes (the "2019 Convertible Notes") with an aggregate principal amount of \$220.0 million issued pursuant to an indenture (the "Indenture") with U.S. Bank National Association, as trustee.

The net proceeds from the sale of the 2019 Convertible Notes were approximately \$212.9 million after deducting the initial purchasers' discounts and commissions of \$6.6 million and offering expenses of \$0.5 million by the Company. The Company used \$28.4 million of the net proceeds from the sale of the 2019 Convertible Notes to pay the cost of the capped call transactions in September 2019 described below.

On May 12, 2020, the Company issued convertible notes (the "2020 Convertible Notes") with an aggregate principal amount of \$300.0 million. The net proceeds from the sale of the 2020 Convertible Notes were approximately \$322.9 million after deducting the purchasers' discounts and commission of \$5.7 million and offering expenses of \$0.3 million. The Company used \$43.1 million of the net proceeds from the sale to pay the cost of the additional capped call transactions in May 2020 described below.

The 2019 Convertible Notes and the 2020 Convertible Notes are referred to together as the Convertible Notes. The Convertible Notes are senior unsecured obligations of the Company and bear interest at a rate of 3.5% per year payable semiannually in arrears on March 15 and September 15 of each year, beginning on March 15, 2020. The Convertible Notes will mature on September 15, 2026, unless converted earlier, redeemed or repurchased in accordance with their terms.

The Convertible Notes are convertible into shares of the Company's common stock at an initial conversion rate of 25.3405 shares per \$1,000 principal amount of Convertible Notes (equivalent to an initial conversion price of approximately \$39.4625 per share of common stock). The conversion rate is subject to customary anti-dilution adjustments. In addition, following certain events that occur prior to the maturity date or if the Company delivers a notice of redemption, the Company will increase the conversion rate for a holder who elects to convert its Convertible Notes in connection with such corporate event or a notice of redemption, as the case may be, in certain circumstances as provided in the Indenture.

Prior to March 15, 2026, the Convertible Notes are convertible only under the following circumstances:

- during any calendar quarter, if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;
- during the five business day period after any five consecutive trading day period in which the trading price per \$1,000 principal amount of the Convertible Notes for each such trading day was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day;
- if the Company calls any or all of the Convertible Notes for redemption, at any time prior to the close of business on the second scheduled trading day immediately preceding the redemption date; or
- upon the occurrence of corporate events specified in the Indenture.

On or after March 15, 2026 until the close of business on the second scheduled trading day immediately preceding the maturity date of the Convertible Notes, holders may convert the Convertible Notes at any time regardless of the foregoing circumstances. Upon conversion of the Convertible Notes, the Company will pay or deliver, as the case may be, cash, shares of the Company's common stock or a combination of cash and shares of common stock, at the Company's election.

Prior to September 20, 2023, the Company may not redeem the Convertible Notes. The Company may redeem for cash all or a portion of the Convertible Notes, at its option, on or after September 20, 2023 if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive), including the trading day immediately preceding the date on which the Company provides a notice of redemption, during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption. The redemption price will be equal to 100% of the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

If the Company undergoes a "fundamental change," as defined in the Indenture, prior to maturity, subject to certain conditions, holders may require the Company to repurchase for cash all or any portion of their Convertible Notes at a fundamental change repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus any accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The Company used an effective interest rate of 10.5% to determine the liability component of the 2019 and 2020 Convertible Notes. This resulted in the recognition of \$145.1 million and \$204.5 million as the liability component of the 2019 and 2020 Convertible Notes, respectively, and the recognition of the residual amount of \$74.9 million and \$95.5 million as the debt discount with a corresponding increase to additional paid in capital for the equity component of the 2019 and 2020 Convertible Notes, respectively. The 2020 Convertible Notes aggregate debt issuance costs of \$6.0 million were allocated to the liability and equity components in the

amounts of \$3.7 and \$2.3 million, respectively. The 2019 Convertible Notes aggregate debt issuance costs of \$7.1 million were allocated to the liability and equity components in the amounts of \$4.7 million and \$2.4 million, respectively.

Effective January 1, 2021, the Company adopted ASU 2020-06 using the modified retrospective method. Upon adoption, the Company increased net debt and reduced net equity by \$149.7 million. The \$149.7 million consisted of several items. The first item is the reclassification from equity to debt of the residual amounts originally identified as the equity components of the 2019 and 2020 Convertible Notes of \$74.9 million and \$95.5 million, respectively. The equity component reclassification was offset by the adjustment to retained earnings for the reversal of previous non-cash interest expense recorded for the amortization of the equity components of \$17.1 million. The second item is the reclassification from equity to debt of the debt issuance costs originally allocated to equity for the 2019 and 2020 Convertible Notes of \$2.4 million and \$2.3 million, respectively. The debt issuance costs reclassification was offset by the adjustment to retained earnings for previous amortization of the debt issuance costs recorded of \$1.1 million.

In January 2021, July 2021 and July 2022, the Company entered into separate, privately negotiated exchange agreements to modify the conversion terms with certain holders of its 2019 Convertible Notes and 2020 Convertible Notes. Under the terms of these exchange agreements, in January 2021, July 2021 and July 2022, the holders exchanged approximately \$126.1 million of 2019 Convertible Notes, \$201.1 million of 2019 Convertible Notes and 2020 Convertible Notes, and \$98.1 million of 2020 Convertible Notes, respectively, in aggregate principal amount held by them for an aggregate of 3,906,869 shares, 5,992,217 shares and 3,027,018 shares, respectively, of common stock issued by the Company. In accordance with FASB ASC Topic 470-20, “*Debt – Debt with Conversion and Other Options*,” (“ASC 470-20”) the Company accounted for the exchange as an induced conversion based on the short period of time the conversion offer was open and the substantive conversion feature offer. The Company accounted for the conversion of the debt as an inducement by expensing the fair value of the shares that were issued in excess of the original terms of the Convertible Notes.

As a result of the January 2021 exchange transactions, the Company reduced net debt outstanding and increased net equity on the consolidated balance sheet by \$122.8 million, consisting of the par value of the 2019 Convertible Notes exchanged of \$126.1 million less the \$3.3 million of remaining debt issuance costs associated with the exchanged notes. The Company also increased shares outstanding by 3,906,869 shares consisting of 3,196,172 shares issued at the initial conversion rate in the Indenture of 25.3405 plus an additional 710,697 shares. Additionally, the Company issued 69,491 shares as settlement of debt issuance costs paid to the Company’s financial advisor in connection with the exchange transaction. For the three months ended March 31, 2021, the Company recorded a loss on conversion of debt of \$39.5 million comprised of \$36.4 million related to the value of the shares issued in excess of the original conversion terms at the fair market value and \$3.1 million for the value of the 69,491 shares issued in payment of issuance costs at their then fair value. Upon exchange of the 2019 Convertible Notes, the holders forfeited accrued interest through the date of the exchange of \$1.7 million, which the Company charged to interest expense and to equity.

As a result of the July 2021 exchange transactions, the Company reduced net debt outstanding and increased net equity on the consolidated balance sheet by \$197.0 million, consisting of the par value of the Convertible Notes exchanged of \$201.1 million less the \$4.1 million of remaining debt issuance costs associated with the exchanged notes. The Company also increased shares outstanding by 5,992,217 shares consisting of 5,097,166 shares issued at the initial conversion rate in the Indenture of 25.3405 plus an additional 895,051 shares. Additionally, the Company issued 78,419 shares as settlement of issuance costs paid to the Company’s financial advisor in connection with the exchange transaction. For the three months ended September 30, 2021, the Company recorded a loss on conversion of debt of \$61.1 million comprised of \$55.9 million related to the value of the shares issued in excess of the original conversion terms at the fair market value and \$5.2 million for the value of the 78,419 shares issued in payment of issuance costs at their then fair value. Upon exchange of the Convertible Notes, the holders forfeited accrued interest through the date of the exchange of \$2.5 million, which the Company charged to interest expense and to equity.

As a result of the July 2022 transactions, the Company reduced net debt outstanding and increased net equity on the consolidated balance sheet by \$96.8 million, consisting of the par value of the Convertible Senior Notes exchanged of \$98.1 million less the \$1.3 million of remaining debt issuance costs associated with the exchanged notes. The Company also increased shares outstanding by 3,027,018 shares consisting of 2,485,548 shares issued at the initial conversion rate in the Indenture of 25.3405 plus an additional 541,470 shares. Additionally, the Company issued 46,132 shares as settlement of issuance costs paid to the Company’s financial advisor in connection with the exchange transaction. For the three months ended September 30, 2022, the Company recorded a loss on conversion of debt of \$32.9 million comprised of \$30.4 million related to the value of the shares issued in excess of the original conversion terms at the fair market value and \$2.5 million for the value of the 46,132 shares issued in payment of issuance costs at their then fair value. Upon exchange of the Convertible Notes, the holders forfeited accrued interest through the date of the exchange of \$1.3 million, which the Company charged to interest expense and to equity.

The conditional conversion feature of the Convertible Notes was triggered as of June 30, 2021, and as a result the Convertible Notes were convertible at the option of the holders until September 30, 2021. During this period, certain holders of the Convertible Notes

converted approximately \$0.7 million of aggregate principal amount of Convertible Notes into an aggregate of 18,775 shares, which were issued in October 2021.

The conditional conversion feature of the Convertible Notes was again triggered as of September 30, 2022, and as a result the Convertible Notes became convertible at the option of the holders. No Convertible Notes were converted through the date of issuance of these unaudited condensed consolidated financial statements.

As of September 30, 2022, the Company held in treasury Convertible Notes in principal amount of \$425.4 million which notes had not been cancelled.

Interest expense for the Convertible Notes was \$1.2 million and \$4.8 million for the three and nine months ended September 30, 2022, respectively. For the three months ended September 30, 2022, interest expense included accrued semi-annual coupon payable of \$1.1 million and amortization of debt issuance costs of \$0.1 million. For the nine months ended September 30, 2022, interest expense included accrued semi-annual coupon payable of \$4.4 million and amortization of debt issuance costs of \$0.4 million. As of September 30, 2022 and December 31, 2021, \$1.2 million and \$3.0 million, respectively, of debt issuance costs were recorded in the unaudited condensed consolidated balance sheet as a reduction to the carrying amount of the Convertible Notes.

Interest expense for the Convertible Notes was \$2.3 million and \$10.2 million for the three and nine months ended September 30, 2021, respectively. For the three months ended September 30, 2021, interest expense included accrued semi-annual coupon payable of \$2.1 million and amortization of debt issuance costs of \$0.2 million. For the nine months ended September 30, 2021, interest expense included accrued semi-annual coupon payable of \$9.4 million and amortization of debt issuance costs of \$0.8 million. As of September 30, 2021, \$3.1 million of debt issuance costs was recorded in the unaudited condensed consolidated balance sheet as a reduction to the carrying amount of the Convertible Notes.

The aggregate principal balance of the Convertible Notes held by third parties, net of unamortized debt issuance costs, as of September 30, 2022 and December 31, 2021 was \$92.7 million and \$189.0 million respectively.

Capped Call Transactions

On September 11, 2019 and May 6, 2020, concurrently with the pricing of the Convertible Notes, the Company entered into capped call transactions with two counterparties. The capped call transactions are expected generally to reduce the potential dilution to the Company's common stock upon any conversion of Convertible Notes and/or offset any cash payments the Company is required to make in excess of the principal amount of converted Convertible Notes, as the case may be, in the event that the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which is initially \$39.4625 (the conversion price of the Convertible Notes) and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of such Convertible Notes. If, however, the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, exceeds the cap price of the capped call transactions, which is initially \$63.14 per share, representing a premium of 100% above the last reported sale price of \$31.57 per share of its common stock on The Nasdaq Global Select Market on September 11, 2019, there would nevertheless be dilution and/or there would not be an offset of such potential cash payments, in each case, to the extent that such market price exceeds the cap price of the capped call transactions.

Pursuant to FASB ASC Topic 815-40 *Derivatives and Hedging*, the Company determined that the capped call transactions should be classified as equity instruments and the capped call premium paid in the amount of \$28.4 million and \$43.1 million were recorded as reductions to additional paid-in capital at December 31, 2021 for the 2019 Convertible Notes and the 2020 Convertible Notes, respectively.

8. Leases

The underlying assets of the Company's leases primarily relate to office space leases, but also include some equipment leases. The Company determines if an arrangement qualifies as a lease at its inception.

As a practical expedient permitted under FASB ASC Topic 842, *Leases*, the Company elected to account for the lease and non-lease components as a single lease component for all leases of which it is the lessee. Lease payments, which may include lease and non-lease components, are included in the measurement of the Company's lease liabilities to the extent that such payments are either fixed amounts or variable amounts that depend on a rate or index as stipulated in the lease contract. When the Company cannot readily determine the rate implicit in the lease, the Company determines its incremental borrowing rate by using the rate of interest that it

would have to pay to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment.

The Company enters into lease agreements with terms generally ranging from 2-7 years. Some of the Company's lease agreements include Company options to extend the lease on a month-to-month basis or for set periods for up to five years. Many of these leases also include options to terminate the leases within one year or per other contractual terms. Renewal and termination options were generally not included in the lease term for the Company's existing operating leases.

As of September 30, 2022 and December 31, 2021, all leases were classified as operating lease assets and liabilities. Additional information related to the operating lease assets and liabilities is as follows (in thousands):

	September 30, 2022	December 31, 2021
Operating Lease Assets	\$ 19,522	\$ 19,901
Operating Lease Liabilities	\$ 20,710	\$ 21,196
Weighted Average Remaining Term in years	3.79	4.66
Weighted Average discount rate used to measure outstanding lease liabilities	7.32 %	7.71 %

For the three months ended September 30, 2022 and 2021, the total lease cost for operating lease expense was \$1.7 million and \$1.4 million, respectively. For the nine months ended September 30, 2022 and 2021, the total lease cost for operating lease expense was \$4.6 million and \$4.2 million, respectively.

Supplemental cash flow information related to operating leases for the nine months ended September 30 is as follows (in thousands):

	2022	2021
Operating cash flows for operating leases	\$ 5,499	\$ 4,476
Operating lease assets obtained in exchange for lease obligations	\$ —	\$ 5,675

The maturities of the Company's operating lease liabilities as of September 30, 2022 are as follows (in thousands):

2022	1,669
2023	6,673
2024	5,913
2025	4,750
2026 and thereafter	4,839
Total future minimum lease payments less	23,844
Imputed interest	(3,134)
Total operating lease liabilities	\$ 20,710

9. Marketable Securities

The amortized cost, gross unrealized holding losses and fair value of available-for-sale debt securities by type of security as of September 30, 2022 and December 31, 2021 were as follows (in thousands):

As of September 30, 2022

	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
U.S. Government-related obligations	\$ 124,746	\$ —	\$ (382)	\$ 124,364

As of December 31, 2021

	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
U.S. Government-related obligations	\$ 60,357	\$ 3	\$ (2)	\$ 60,358

All available-for-sale securities mature in one year or less.

10. Other Comprehensive Income and Accumulated Other Comprehensive Income

The following tables summarize the changes in accumulated other comprehensive income/(loss), by component for the nine months ended September 30, 2022 and September 30, 2021 (in thousands):

	Unrealized Gains (Losses) from Marketable Securities	Foreign Currency Translation Adjustment	Total Accumulated Other Comprehensive Income (Loss)
Balances, December 31, 2021	\$ 1	\$ (2,091)	\$ (2,090)
Net other comprehensive income (loss)	(52)	83	31
Balances, March 31, 2022	(51)	(2,008)	(2,059)
Net other comprehensive loss	(766)	(369)	(1,135)
Balances, June 30, 2022	(817)	(2,377)	(3,194)
Net other comprehensive income (loss)	435	(268)	167
Balances, September 30, 2022	\$ (382)	\$ (2,645)	\$ (3,027)

	Unrealized Gains (Losses) from Marketable Securities	Foreign Currency Translation Adjustment	Total Accumulated Other Comprehensive Income (Loss)
Balances, December 31, 2020	\$ (8)	\$ (109)	\$ (117)
Net other comprehensive income (loss)	79	(1,582)	(1,503)
Balances, March 31, 2021	71	(1,691)	(1,620)
Net other comprehensive loss	(35)	(174)	(209)
Balances, June 30, 2021	36	(1,865)	(1,829)
Net other comprehensive income (loss)	(25)	(156)	(181)
Balances, September 30, 2021	\$ 11	\$ (2,021)	\$ (2,010)

11. Fair Value Measurements

The Company is required to disclose information on the fair value of financial instruments and inputs that enable an assessment of the fair value. The three levels of the fair value hierarchy prioritize valuation inputs based upon the observable nature of those inputs as follows:

Level 1 – Quoted prices in active markets for identical assets or liabilities;

Level 2 – Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly;

Level 3 – Unobservable inputs that reflect the Company’s own assumptions about the assumptions market participants would use in pricing the asset or liability.

The following table presents the fair value of financial instruments recorded originally at amortized cost or fair value and not remeasured on a recurring basis (in thousands):

		September 30, 2022			
Balance Sheet Classification	Type of Instrument	Level 1	Level 2	Level 3	Total
Financial Assets:					
Cash and cash equivalents:	Money market funds	\$ 540,297	\$ —	\$ —	\$ 540,297
Total Financial Assets		<u>\$ 540,297</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 540,297</u>

		December 31, 2021			
Balance Sheet Classification	Type of Instrument	Level 1	Level 2	Level 3	Total
Financial Assets:					
Cash and cash equivalents	Money market funds	\$ 598,833	\$ —	\$ —	\$ 598,833
Total Financial Assets		<u>\$ 598,833</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 598,833</u>

The following table presents the fair value of financial instruments recorded at fair value at inception and remeasured on a recurring basis (in thousands):

		September 30, 2022			
Balance Sheet Classification	Type of Instrument	Level 1	Level 2	Level 3	Total
Financial Assets:					
Marketable securities:	US government obligations	\$ 124,364	\$ —	\$ —	\$ 124,364
Total Financial Assets		<u>\$ 124,364</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 124,364</u>

		December 31, 2021			
Balance Sheet Classification	Type of Instrument	Level 1	Level 2	Level 3	Total
Financial Assets:					
Marketable securities:	US government obligations	\$ 60,358	\$ —	\$ —	\$ 60,358
Total Financial Assets		<u>\$ 60,358</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 60,358</u>

The Company’s Convertible Notes and development liability are financial instruments that are reported in the consolidated financial statements at historical cost. The Convertible Notes are Level 1 within the fair value level hierarchy as of September 30, 2022 and December 31, 2021. The fair value of the Convertible Notes was \$177.5 million as of September 30, 2022 and \$290.7 million as of December 31, 2021. The Convertible Notes accrue a semi-annual coupon at an annual rate of 3.5%, which was included in accrued expenses in the consolidated balance sheets as of September 30, 2022 and December 31, 2021.

The fair value of the development liability was \$320.0 million and \$352.7 million as of September 30, 2022 and December 31, 2021, respectively. The development liability is Level 2 within the fair value hierarchy based on the discounting of fixed cash flows using an observed bond yield for borrowers with similar credit rating.

12. Income Taxes

For the three and nine months ended September 30, 2022, the Company recorded \$0.4 million and \$2.1 million of income tax expense, respectively, primarily pertaining to federal and state income taxes where the utilization of net operating losses and research and development tax credits are limited. There was no income tax provision for the three months and nine months ended September 30, 2021.

The income tax provision during interim periods is computed by applying an estimated annual effective tax rate to year-to-date pre-tax income, plus adjustments for significant unusual or infrequently occurring items, in accordance with FASB ASC Topic 740-270, *Income Taxes – Interim Reporting*. The income tax provision differs from the U.S. federal statutory rate of 21% primarily due to the effect of valuation allowance against the Company's net deferred tax assets, which reduces the Company's net tax benefit.

Deferred tax assets and deferred tax liabilities are determined based on temporary differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company has recorded a full valuation allowance against its net deferred tax assets for the period ended September 30, 2022.

The Company does not recognize a tax benefit for uncertain tax positions unless it is more likely than not that the position will be sustained upon examination by tax authorities, including resolution of any related appeals or litigation processes, based on the technical merits of the position. The tax benefit that is recorded for these positions is measured at the largest amount of cumulative benefit that has greater than a 50 percent likelihood of being realized upon ultimate settlement. Deferred tax assets that do not meet these recognition criteria are not recorded and the Company recognizes a liability for uncertain tax positions that may result in tax payments. The Company recorded \$1.9 million of unrecognized tax benefits for the period ended September 30, 2022. If such unrecognized tax benefits were realized, the entire amount would impact the tax provision. Our policy is to review and update unrecognized tax positions as facts and circumstances change.

13. License and Collaboration Agreements

Sobi License and Collaboration Agreement

On October 27, 2020, the Company and its subsidiaries, Apellis Switzerland GmbH and APL DEL Holdings, LLC entered into a Collaboration and License Agreement (the "Sobi collaboration agreement") with Swedish Orphan Biovitrum AB (Publ) ("Sobi"), concerning the development and commercialization of pegcetacoplan and specified other structurally and functionally similar compstatin analogues or derivatives for use systemically or for local non-ophthalmological administration (collectively referred to as the "Licensed Products").

Under the Sobi collaboration agreement, the Company granted Sobi an exclusive (subject to certain retained rights of the Company), sublicensable license of certain patent rights and know-how to develop and commercialize Licensed Products in all countries outside of the United States. The Company retains the right to commercialize Licensed Products in the United States, and, subject to specified limitations, to develop Licensed Products worldwide for commercialization in the United States.

Under the Sobi collaboration agreement, the Company and Sobi have agreed to collaborate to develop Licensed Products for the treatment of PNH, cold agglutinin disease, hematopoietic stem cell transplantation-associated thrombotic microangiopathy, C3 glomerulopathy and immune complex membranoproliferative glomerulonephritis, and amyotrophic lateral sclerosis (collectively the "Initial Indications"), and any other indications subsequently agreed upon by the parties, for commercialization by or on behalf of the Company in the United States and by or on behalf of Sobi outside of the United States. If the parties do not agree to jointly pursue any development activities for the Licensed Products (whether for an Initial Indication or otherwise), the party proposing to pursue such activities may conduct such activities at its sole expense (with the non-proposing party having the right to obtain rights to the data generated by such development activities by paying a specified percentage of that expense), subject to agreed-upon exceptions that limit each party's unilateral development rights.

The initial development plan sets forth the initial development activities to be conducted by each of the Company and Sobi, with the Company bearing all costs incurred in conducting the activities set forth in such initial development plan, as well as certain specified additional costs that are not included in the initial development plan that may be incurred by the parties in developing Licensed Products for PNH in the European Union and the United Kingdom. The Company and Sobi have formed several governance committees to oversee the development and manufacture, and to review and discuss the commercialization, of Licensed Products.

The Company shall supply Licensed Products to Sobi for development and for commercialization outside of the United States in accordance with a supply agreement to be negotiated by the parties. The collaboration agreement grants Sobi the right to perform or have performed drug product manufacturing of Licensed Products for development and for commercialization outside the United States and to manufacture or have manufactured drug substance under certain circumstances.

Sobi paid the Company an upfront payment of \$250.0 million in November 2020 and has agreed to pay up to an aggregate of \$915.0 million upon the achievement of specified one-time regulatory development and commercial milestone events, of which the Company received \$50.0 million in April 2022 for the achievement of a regulatory development milestone in Europe. Sobi also agreed to reimburse the Company for up to \$80.0 million in development costs, of which the Company received \$25.0 million in January 2021 and \$20.0 million in January 2022. The Company will also be entitled to receive tiered, double-digit royalties (ranging from high teens to high twenties) on sales of Licensed Products outside of the United States, subject to customary deductions and third-party payment obligations, until the latest to occur of: (i) expiration of the last-to-expire of specified licensed patent rights; (ii) expiration of regulatory exclusivity; and (iii) ten (10) years after the first commercial sale of the applicable Licensed Product, in each case on a Licensed Product-by-Licensed Product and country-by-country basis. Under the Sobi collaboration agreement, the Company remains responsible for its license fee obligations (including royalty obligations) to the University of Pennsylvania as a licensor of the Company and for its payment obligations to SFJ.

Sobi Accounting Analysis

The Company has determined that the Sobi collaboration agreement is within the scope of FASB ASC Topic 808, *Collaborative Arrangement Guidance and Considerations*, (“ASC 808”) as a contractual arrangement that involves a joint operating activity whereby both parties are (i) active participants in the activity and (ii) exposed to certain significant risks and rewards dependent on the commercial success of the activity. ASC 808 does not address measurement or recognition matters but allows for analogizing to FASB ASC Topic 606, *Revenue from Contracts with Customers*, (“ASC 606”). Pursuant to ASC 606, the Company performed the following five steps: (i) identified the contract(s) with a customer; (ii) identified the performance obligations in the contract; (iii) determined the transaction price; (iv) allocated the transaction price to the performance obligations in the contract; and (v) recognized revenue when (or as) the entity satisfies a performance obligation.

The Company identified the following material distinct promises under the Sobi collaboration agreement: (1) licenses to develop and commercialize pegcetacoplan (“Licenses to IP”), and (2) performance of research and development services. The Company determined the promises to be distinct because Sobi can benefit from each of the license and the development services on their own or with readily available services. The Company could have provided the license without any development services and Sobi would have been able to benefit from it by obtaining development services from another provider as the Licensed Products are at a more mature stage in their life cycle.

Under the Sobi collaboration agreement, Sobi agreed to pay the Company

- i) a fixed amount of \$250.0 million in an upfront payment in November 2020;
- ii) a fixed amount of an additional \$80.0 million in development reimbursements, payable yearly in four tranches in amounts determined based upon actual expenses incurred by the Company;
- iii) up to an aggregate of \$915.0 million upon the achievement of specified one-time regulatory and commercial milestone events; and
- iv) tiered, double-digit royalties, ranging from high teens to high twenties, on sales of Licensed Products outside of the United States, subject to customary deductions and third-party payment obligations.

At contract inception, the \$250.0 million non-refundable payment and the \$80.0 million reimbursements were fixed proceeds. The Company evaluated whether Sobi is a customer for either of the distinct promises in the Sobi collaboration agreement. Under the Licenses to IP, the Company determined that Sobi is a customer as the know-how provided and the right granted by the Company to Sobi are outputs of the Company’s business activities for which the Company will receive consideration. With respect to research and development activity, management determined that there is no vendor relationship as performing research and development activities for others is not a part of the Company’s ongoing central operations. Based upon the evaluation of the relative fair values, the Company allocated the purchase price of \$250.0 million and the related milestones and royalties to the License to IP and \$80.0 million to performance of research and development activities.

The milestone and royalty payments are subject to activities outside the control of the Company. Per ASC 606, the Company considers this to be a customer/ vendor relationship, therefore, the Company will include the regulatory milestone payments in the

total transaction price when it is probable that a significant reversal of revenue would not occur in a future period. The Company will recognize commercial milestone and royalty revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which the commercial milestone or royalty has been allocated has been satisfied. In case of commercial milestone or royalty payments, the Company will recognize revenue in the same period that the sales are completed for which the Company is contractually entitled to the milestone or percentage-based royalty payment. To date, the Company has not recognized any commercial milestone revenue resulting from any of its licensing arrangements. The Company has recognized \$0.8 million and \$1.6 million of royalty revenue for the three and nine months ended September 30, 2022, respectively. Management periodically assesses the elements of the contract and re-evaluates revenue recognition as necessary.

Pursuant to ASC 606, during the year ended December 31, 2020, the Company recognized the \$250.0 million in revenue as this is the amount allocated to the license. The \$80.0 million reimbursement for research and development activities does not constitute a customer/vendor relationship and thus is not in the scope of ASC 606. As ASC 808 does not include recognition guidance, the Company has established an accounting policy to recognize the payments under the reimbursement as a receivable on the consolidated balance sheet in an amount that is to be reimbursed based upon expense incurred by the Company, with a contra-research and development expense recognized in the consolidated statement of operations, over time as the expenses are incurred.

Under the Sobi collaboration agreement, for the three and nine months ended September 30, 2022 and 2021, the Company did not recognize licensing revenue. For the three and nine months ended September 30, 2022, the Company recognized \$0.8 million and \$1.6 million, respectively, of royalty revenue. The Company did not recognize any royalty revenue for the three and nine months ended September 30, 2021. For the nine months ended September 30, 2022, the Company recognized \$5.0 million for contra-research and development expense in the unaudited condensed consolidated statement of operations related to the \$80.0 million reimbursement commitment from Sobi. The Company did not recognize any contra-research and development expense for the three months ended September 30, 2022. For the three and nine months ended September 30, 2021, the Company recognized \$6.4 million and \$23.6 million, respectively, for contra-research and development expense. Since contract inception, the Company has recognized \$80.0 million in contra-research and development expenses.

As of September 30, 2022, the Company recorded a receivable of \$35.0 million, with \$20.0 million in current assets and \$15.0 million in long-term assets, on the unaudited condensed consolidated balance sheet. The total receivable balance as of September 30, 2022 is for contra-research and development expenses incurred but not yet reimbursed from Sobi.

As of December 31, 2021, the Company recorded a receivable of \$100.0 million, with \$70.0 million in current assets and \$30.0 million in long-term assets. Of the \$100.0 million receivable as of December 31, 2021, \$50.0 million is for contra-research and development reimbursement from Sobi, with \$20.0 million and \$30.0 million in current and long-term assets, respectively. The remaining \$50.0 million receivable as of December 31, 2021 in current assets is for the achievement of the development milestone for first regulatory and reimbursement approval in Europe.

University of Pennsylvania License Agreement

The Company is a party to a license agreement with the Trustees of the University of Pennsylvania (“Penn”) for an exclusive, worldwide license to specified patent rights. The Company is required to pay annual maintenance fees of \$0.1 million until the first sale of a licensed product. The Company is also required to make milestone payments aggregating up to \$3.2 million based upon the achievement of specified development and regulatory milestones and up to \$5.0 million based upon the achievement of specified annual sales milestones with respect to each licensed product, and to pay low single-digit royalties based on net sales of each licensed product and with minimum quarterly royalty thresholds. In addition, the Company is obligated to pay a specified portion of income it receives from sublicensees.

In addition, the Company is also party to a license agreement with Penn for an exclusive, worldwide license to specified patent rights for the development and commercialization of products in fields of use, as defined therein. The Company is required to pay annual maintenance fees of \$0.1 million until the first sale of a licensed product. The Company is required to make milestone payments aggregating up to \$1.7 million, based upon the achievement of development and regulatory approval milestones, and up to \$2.5 million, based upon the achievement of annual sales milestones with respect to each of the first two licensed products. The license agreement also requires the Company to pay low single digit royalties based on net sales of each licensed product, subject to minimum quarterly royalty thresholds. In addition, the Company is obligated to pay a specified portion of income it receives from sublicensees. In January 2021, the Company paid \$25.0 million for a sublicense fee owed to Penn related to the Sobi collaboration agreement and another licensing transaction. In August 2021 the Company paid \$1.0 million to Penn upon the achievement of a development milestone. In June 2022 the Company paid an additional \$5.0 million to Penn upon the achievement of a development milestone, which was accrued as of December 31, 2021, as it was considered probable at that time. The \$5.0 million development milestone was recorded in accrued expenses on the unaudited condensed consolidated balance sheet as of December 31, 2021.

Beam Research Collaboration

In June 2021, the Company entered into an exclusive five-year research collaboration (the “Beam collaboration agreement”) with Beam Therapeutics, Inc. (“Beam”) focused on the use of Beam’s proprietary base editing technology to discover new treatments for complement-driven diseases. The Company and Beam agreed to collaborate on up to six research programs focused on C3 and other complement targets in the eye, liver and brain. Under the terms of the Beam collaboration agreement, Apellis is responsible for selecting specific genes within the complement system in various organs including the eye, liver and brain (the “Target List”) and providing analytical support while Beam will apply its base editing technology and conduct preclinical research on up to six base editing programs for the Target List. During the first five years of the Beam collaboration agreement, Beam is prohibited from developing on its own or with a third party any base editing therapies associated with the items on the Target List but does not prevent Beam from licensing its intellectual property to a third-party for another purpose outside of the Target List. The Company will have exclusive rights to license each of the six programs and will assume responsibility for subsequent development and commercialization. Beam may elect to enter a 50-50 co-development and U.S. co-commercialization agreement with the Company with respect to any one program licensed under the Beam collaboration agreement and upon such election any license agreement in place at that time, would be terminated.

As part of the Beam collaboration agreement, the Company agreed to pay a \$50.0 million up-front, non-refundable payment to Beam, which the Company paid in July 2021. In June 2022, the Company paid \$25.0 million which was recorded as a cost of research collaboration expense for the year ended December 31, 2021, as it was considered probable of achievement. The Company and Beam are each responsible for their own costs during the research collaboration. If and after the opt-in license rights are exercised for each of the up to six programs, Beam will be eligible to receive development, regulatory and sales milestones from the Company, as well as royalty payments on sales. The Beam collaboration agreement has an initial term of five years and may be extended up to two years on a per year program-by-program basis.

The Company analyzed the Beam research collaboration agreement pursuant to ASC 808 to assess whether the agreement involved joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. Since each party is actively participating in this activity and exposed to significant risks and rewards related to the activity through each party’s costs will be accounted for under ASC 808.

Since ASC 808 does not provide recognition guidance, the Company referred to the guidance under FASB ASC Topic 730, *Research and Development* (“ASC 730”), to arrangements involving payments by the Company. ASC 730 requires the Company to recognize research and development costs as expense as incurred since the payment was made for the use of Beam’s intellectual property and research and development services and there is no alternative use.

14. Commitments and Contingencies

The Company has certain non-cancelable purchase obligations related to the manufacturing of drug substance and drug product with Bachem Americas, Inc. and Bachem AG, under which the Company has agreed to purchase a significant portion of its requirements for the pegcetacoplan drug substance over the next five years, and a commercial supply agreement with NOF Corporation, under which the Company has agreed to purchase activated polyethylene glycol derivative, or PEG, which is a component of pegcetacoplan. Under these agreements, as of September 30, 2022, the Company is obligated to pay up to \$112.1 million to these vendors. In addition, the Company has other non-cancelable purchase agreements as of September 30, 2022, under which it is obligated to pay up to \$6.2 million to these vendors.

Following regulatory approval by the FDA and EMA for the use of pegcetacoplan as a treatment for PNH, the Company has certain payment and other obligations under the SFJ agreement, which are discussed above in Note 6 Development Liability and Development Derivative Liability.

The Company is a party to a master lease agreement under which the Company leases vehicles with initial terms of 36 months from the date of delivery. If the Company were unable to take delivery of a previously ordered vehicle, the Company may incur nominal fees.

Indemnifications—In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend indemnified parties for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has not incurred any cost to defend lawsuits or settle claims related to these indemnification provisions.

Legal—During the normal course of business, the Company may be a party to legal claims that may not be covered by insurance. Management does not believe that any such claims would have a material impact on the Company’s consolidated financial statements.

15. Net Loss per Share

Since the Company was in a loss position for all periods presented, basic net loss per common share is the same as diluted net loss per common share for all periods presented as the inclusion of all potential common shares outstanding would have been anti-dilutive. Convertible notes and shares outstanding presented below were excluded from the calculation of diluted net loss per share, prior to the use of the treasury stock method, as their effect is anti-dilutive (in thousands):

	As of September 30,	
	2022	2021
Convertible notes	2,379	4,884
Common stock options	12,511	12,954
Restricted stock units	3,568	1,071
Total	<u>18,458</u>	<u>18,909</u>

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and related notes for the year ended December 31, 2021 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2022, which we refer to as the 2021 Annual Report on Form 10-K.

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Please also refer to those factors described in "Part I, Item 1A. Risk Factors" of our 2021 Annual Report on Form 10-K for important factors that we believe could cause actual results to differ materially from those in our forward-looking statements.

Overview

We are a commercial-stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutic compounds to treat diseases with high unmet needs through the inhibition of the complement system, which is an integral component of the immune system, at the level of C3, the central protein in the complement cascade. We believe that this approach can result in broad inhibition of the principal pathways of the complement system and has the potential to effectively control a broad array of complement-dependent autoimmune and inflammatory diseases.

In May 2021, the U.S. Food and Drug Administration, or the FDA, approved EMPAVELI® (pegcetacoplan), the first targeted C3 therapy and our first approved product, for the treatment of paroxysmal nocturnal hemoglobinuria, or PNH. EMPAVELI is approved for use in adults with PNH and can be used by patients who are either treatment-naïve or who are switching from C5 inhibitors eculizumab or ravulizumab. We believe that EMPAVELI has the potential to elevate the standard of care in PNH and are seeking to establish EMPAVELI as the preferred first-line treatment for patients. In the United States, there are approximately 1,500 patients with PNH currently being treated with C5 inhibitors and another 150 patients who are expected to be newly diagnosed each year. Since our launch of EMPAVELI in May 2021 through September 30, 2022, we generated \$60.5 million in net product revenue from sales. For the three and nine months ended September 30, 2022, we generated \$17.7 million and \$45.4 million, respectively, in net product revenue from sales of EMPAVELI.

In December 2021, the European Commission, or the EC, approved Aspaveli® (pegcetacoplan) for the treatment of adults with PNH who are anemic after treatment with a C5 inhibitor for at least three months. To date, systemic pegcetacoplan has also been approved for the treatment of PNH in Saudi Arabia, Australia, and the United Kingdom. Systemic pegcetacoplan is currently marketed under the trade name EMPAVELI™ in the United States, Saudi Arabia and Australia and Aspaveli in the European Union and United Kingdom. Under our collaboration and license agreement, or the Sobi collaboration agreement, with Swedish Orphan Biovitrum AB (Publ), or Sobi, Sobi has global co-development and exclusive ex-U.S. commercialization rights for systemic pegcetacoplan and initiated the commercial launch of EMPAVELI/Aspaveli in jurisdictions outside of the United States during the first quarter of 2022. We have commercialization rights for systemic pegcetacoplan in the United States.

We also are leveraging our expertise in targeting C3 to advance intravitreal pegcetacoplan as the first potential treatment for geographic atrophy, or GA, secondary to age-related macular degeneration, or AMD. We believe that intravitreal pegcetacoplan has the potential to be a breakthrough for patients with GA, a disease that affects approximately one million people in the United States and five million people worldwide. Based on the results of our Phase 3 (DERBY and OAKS) and Phase 2 (FILLY) clinical trials of intravitreal pegcetacoplan, we submitted a new drug application, or NDA, to the FDA in June 2022 with a request for six-month priority review. In July 2022, the FDA accepted the NDA and granted priority review with a Prescription Drug User Fee Act (PDUFA) target action date of November 26, 2022. In August 2022, we announced 24-month top-line data showing increased effects over time with intravitreal pegcetacoplan in the Phase 3 DERBY and OAKS clinical trials in GA. We plan to submit the 24-month efficacy data from DERBY and OAKS in a major amendment to the NDA, which would extend the review period by three months

with an expected PDUFA target action date in February 2023. The 24-month safety data were previously submitted as part of the 120-day update. The FDA has stated that it is not planning to hold an advisory committee meeting to discuss the NDA. We plan to submit a market authorization application, or MAA, to the European Medicines Agency, or the EMA, in December 2022.

We have exclusive, worldwide commercialization rights for intravitreal pegcetacoplan.

We believe that inhibition of the complement system by targeting C3 may enable a broad range of therapeutic approaches, and that pegcetacoplan has the potential to address the limitations of existing treatment options or provide a treatment option in indications where there currently are none. Under our collaboration with Sobi, we are co-developing systemic pegcetacoplan for cold agglutinin disease, or CAD, and hematopoietic stem cell transplantation-associated thrombotic microangiopathy, or HSCT-TMA, in hematology; C3 glomerulopathy, or C3G, and immune complex membranoproliferative glomerulonephritis, or IC-MPGN, in nephrology; and amyotrophic lateral sclerosis, or ALS, in neurology.

We are also evaluating the administration of systemic pegcetacoplan as an approach to enabling adeno-associated virus, or AAV, vector administration for gene therapies. We believe complement inhibition may yield important benefits when used in combination with AAV-delivered gene therapies, such as increasing the safety of AAV-delivered gene therapies, decreasing the required AAV dose needed to achieve a therapeutic effect, and allowing for dosing in patients who have pre-existing antibodies. In collaboration with commercial and academic researchers, we are advancing pre-clinical studies to assess the impact of complement inhibition on AAV-delivered gene therapies.

Lastly, we are developing additional product candidates with other routes of administration and plan to conduct clinical trials of these product candidates, including the combination of EMPAVELI and a small interfering RNA, or siRNA, which may offer the potential to reduce the treatment frequency of EMPAVELI by reducing the production of C3 proteins in the liver. Furthermore, we are collaborating with Beam Therapeutics, Inc., or Beam, on up to six research programs focused on C3 and other complement targets in the eye, liver and brain, using Beam's proprietary base editing technology to discover new treatments for complement-driven diseases.

Intravitreal Pegcetacoplan. In September 2021, we reported top-line data from our Phase 3 clinical program consisting of two Phase 3 clinical trials evaluating intravitreal pegcetacoplan in patients with GA.

In August 2022, we announced top-line data at 24 months from DERBY and OAKS showing increased effects over time with intravitreal pegcetacoplan in GA (all p-values are nominal). In OAKS, monthly and every-other-month treatment with intravitreal pegcetacoplan reduced GA lesion growth by 22% ($p < 0.0001$) and 18% ($p = 0.0002$), respectively. In DERBY, monthly and every-other-month treatment with intravitreal pegcetacoplan reduced GA lesion growth by 19% ($p = 0.0004$) and 16% ($p = 0.0030$), respectively.

Between months 18-24, the pegcetacoplan treatment effect accelerated compared to previous six-month periods, with reductions of GA lesion growth of 30% and 24% in the monthly and every-other-month arms, respectively, with nominal p-values of < 0.0001 in both arms, when compared against pooled sham (all p-values are nominal). Additionally, the reduction of GA lesion growth in patients with extrafoveal lesions (28% monthly; 28% every-other-month) was comparable to the reduction in patients with foveal lesions (34% monthly; 28% every-other-month) in the combined studies between months 18-24.

Consistent with expectations, no clinically meaningful difference was observed between pegcetacoplan and sham in the key secondary outcomes measuring visual function at 24 months, including best corrected visual acuity and microperimetry. Studies show that GA lesion growth is correlated with loss of visual function over longer periods of time. The visual function outcomes at 24 months are believed to be due to the limitations of the endpoints when used for GA and the relatively early assessment timeframe.

Pegcetacoplan continued to demonstrate a favorable safety profile, consistent with safety data to date and longer-term exposure to intravitreal injections. The combined rate of new-onset exudations at month 24 was 11.9%, 6.7%, and 3.1% in the pegcetacoplan monthly, every-other-month, and sham groups, respectively.

Patients will be treated with pegcetacoplan in the GALE open label extension study for an additional three years. All patients who completed the DERBY or OAKS studies were invited to participate in the GALE study.

The results at 24 months will be included in the marketing authorization application, or MAA, that the Company plans to submit to the European Medicines Agency, or EMA, in December 2022.

At the American Academy of Ophthalmology Annual Meeting in October 2022, two post hoc analyses were presented providing further evidence that treatment of GA with intravitreal pegcetacoplan reduces photoreceptor loss and has the potential to preserve visual function. This included an analysis of microperimetry data at 24 months demonstrating that both every-other-month and

monthly pegcetacoplan treatment preserved visual function of retinal cells near the GA lesion border compared to sham. Additionally, a post hoc AI-guided analysis of OCT images from DERBY and OAKS at 12 months showed a substantial and rapid reduction in photoreceptor loss for both monthly and every-other-month pegcetacoplan in GA patients, reinforcing the robust efficacy of pegcetacoplan in preserving photoreceptors, which are responsible for vision. This second analysis was conducted by The Medical University of Vienna and RetinSight Inc.

In November 2022, we announced our plans to submit the 24-month efficacy data from DERBY and OAKS in a major amendment to the NDA, which would extend the review period by three months with an expected PDUFA target action date in February 2023. The 24-month safety data were previously submitted as part of the 120-day update.

We have built out our ophthalmology team in the United States with leadership positions in place across medical affairs, marketing and sales, and market access, and we have also begun to build out our European team and affiliates in Germany and Australia.

Systemic Pegcetacoplan. In addition to PNH, for which we obtained approval in the United States, we are developing systemic pegcetacoplan in collaboration with Sobi in several other indications, including C3G, IC-MPGN, ALS, CAD and HSCT-TMA.

PNH. In May 2021, the FDA approved systemic pegcetacoplan for the treatment of adult patients with PNH. EMPAVELI is approved for use in adults with PNH and can be used by patients who are either treatment-naïve or who are switching from C5 inhibitors eculizumab or ravulizumab. We believe that EMPAVELI has the potential to elevate the standard of care in PNH and are seeking to establish EMPAVELI as the preferred first-line treatment for patients. In the United States, there are approximately 1,500 patients with PNH currently being treated with C5 inhibitors and another 150 patients who are expected to be newly diagnosed each year.

In December 2021, the EC approved Aspaveli for the treatment of adults with PNH who are anemic after treatment with a C5 inhibitor for at least three months. To date, systemic pegcetacoplan has also been approved for the treatment of PNH in Saudi Arabia, Australia, and the United Kingdom. Systemic pegcetacoplan is currently marketed under the trade name EMPAVELI™ in the United States, Saudi Arabia and Australia and Aspaveli in the European Union and United Kingdom. Under our collaboration and license agreement with Sobi, Sobi has global co-development and exclusive ex-U.S. commercialization rights for systemic pegcetacoplan and initiated the commercial launch of Aspaveli in jurisdictions outside of the United States during the first quarter of 2022. We have commercialization rights for systemic pegcetacoplan in the United States.

C3G/IC-MPGN. We have initiated and plan to continue to lead our registrational program in C3G / IC-MPGN. We dosed the first patient in the NOBLE trial in up to 12 patients with post-kidney transplant recurrence of C3G or IC-MPGN in September of 2021. In June 2022, we dosed the first patient in our Phase 3 VALIANT trial. VALIANT is a randomized, placebo-controlled, double-blinded, multi-center Phase 3 trial being conducted in approximately 90 patients who are 12 years of age and older with primary IC-MPGN or C3G. VALIANT is the only study to include both native kidney patients and patients who have recurrent disease after receiving a kidney transplant.

ALS. In March 2022, we completed enrollment in MERIDIAN, our randomized, placebo-controlled Phase 2 clinical trial of systemic pegcetacoplan in adults with sporadic ALS. The trial enrolled approximately 250 adults. Trial participants are randomized in a 2:1 ratio to receive pegcetacoplan or placebo while continuing to receive their existing standard of care treatment for ALS. After 52 weeks of blinded treatment, all patients in the study will receive pegcetacoplan. We expect to report top-line data from this trial in mid-2023.

CAD and HSCT-TMA. Sobi is leading development activities for a Phase 3 clinical trial in CAD and a Phase 2 clinical trial in HSCT-TMA. In early 2022, Sobi dosed the first patient in the Phase 2 clinical trial of systemic pegcetacoplan in patients with HSCT-TMA. In October 2022, Sobi dosed the first patient in the Phase 3 clinical trial of systemic pegcetacoplan in patients with CAD.

Pipeline. We are developing pegcetacoplan in multiple indications and other product candidates targeting C3 through various routes of administration. We plan to conduct clinical trials of our product candidates in additional complement-dependent indications.

We plan to advance up to three new product candidates into clinical development in 2023. These candidates include a siRNA treatment designed to reduce the production of C3 proteins by the liver; an oral alternative pathway inhibitor for certain renal conditions; and a novel compound designed to treat both GA and wet AMD by intravitreal administration. We also plan to continue our research activities under collaboration with Beam to develop gene-editing therapies in multiple therapeutic areas.

Since our commencement of operations in May 2010, we have devoted substantially all of our resources to developing our proprietary technology, developing product candidates, undertaking preclinical studies and conducting clinical trials for pegcetacoplan, building our intellectual property portfolio, organizing and staffing our company, business planning, raising capital, preparing for and executing the commercial launch of our products and providing general and administrative support for these operations.

As of September 30, 2022, we had cash, cash equivalents and marketable securities of \$708.6 million. We believe that our cash and cash equivalents and marketable securities, along with cash anticipated to be generated from sales of EMPAVELI and from intravitreal pegcetacoplan for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) and, committed development reimbursement payments from Sobi as of September 30, 2022, will be sufficient to enable us to fund our current operations at least into the first quarter of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. For additional information see “Liquidity and Capital Resources.”

Since the launch of EMPAVELI in May 2021 through September 30, 2022, we have generated \$60.5 million of net product revenue from sales. We have incurred significant annual net operating losses in each year since our inception and expect to continue to incur net operating losses for the foreseeable future. Our net losses were \$191.3 million and \$195.6 million for the three months ended September 30, 2022 and, 2021, respectively, and \$486.2 million and \$598.4 million for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, we had an accumulated deficit of \$2.1 billion.

Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase significantly particularly as we continue to incur significant commercialization expenses related to building sales, marketing, medical affairs, manufacturing, distribution and other commercial infrastructure associated with the commercialization of EMPAVELI for the treatment of PNH. We are incurring significant expenses for the commercialization and further development of intravitreal pegcetacoplan. In addition, we expect our expenses to increase if and as we continue to develop and conduct our ongoing and planned clinical trials of pegcetacoplan and our other product candidates; initiate and continue research and preclinical and clinical development efforts for any future product candidates; seek to identify and develop additional product candidates for complement-dependent diseases; seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any; establish sales, marketing, distribution and other commercial infrastructure to commercialize any additional products for which we may obtain marketing approval; require the manufacture of larger quantities of product candidates for clinical development and, potentially, commercialization; maintain, expand and protect our intellectual property portfolio; hire and retain additional personnel, such as clinical, quality control, regulatory and scientific personnel; add operational, financial and management information systems and personnel, including personnel to support our product development and add equipment and physical infrastructure to support our research and development programs and commercialization.

We temporarily closed our facilities in March 2020 in respect to the COVID-19 pandemic. We have since reopened our facilities, subject to compliance with strict safety guidelines, but many of our employees continue to work remotely. As of the date of this Quarterly Report on Form 10-Q, we do not believe that the COVID-19 pandemic has had a significant impact upon our operations, including sales of EMPAVELI (except to the extent that our representatives’ access to the offices of health care providers was limited during the omicron wave of the pandemic), our ongoing clinical trials (except for the delay of the clinical trials for ALS) and the manufacture and supply of our product candidates.

SFJ Agreement

On February 28, 2019, we entered into a development funding agreement, which we refer to as the SFJ agreement, with SFJ Pharmaceuticals Group, or SFJ, under which SFJ agreed to provide funding to us to support the development of systemic pegcetacoplan for the treatment of patients with PNH. Pursuant to the agreement, SFJ paid us \$60.0 million following the signing of the agreement and agreed to pay us up to an additional \$60.0 million in the aggregate in three equal installments upon the achievement of specified development milestones with respect to our Phase 3 program for pegcetacoplan in PNH and subject to our having cash resources at the time sufficient to fund at least 10 months of our operations.

On June 7, 2019, we amended the SFJ agreement, which we refer to as the SFJ amendment. Under the SFJ amendment, SFJ agreed to make an additional \$20.0 million funding payment to us to support the development of systemic pegcetacoplan for the treatment of patients with PNH.

On June 27, 2019, we received \$40.0 million from SFJ, consisting of \$20.0 million as the first installment of the additional \$60.0 million upon the achievement of a milestone and the \$20.0 million payable under the SFJ amendment.

In September 2019, we received \$20.0 million from SFJ, as the second installment of the additional \$60.0 million due to the achievement of a milestone and in January 2020 received the remaining \$20.0 million installment of the additional \$60.0 million upon the announcement of the results of the PEGASUS phase 3 trial.

Under the SFJ agreement, following regulatory approvals by the FDA and the EMA for the use of systemic pegcetacoplan as a treatment for PNH, we paid SFJ \$4.0 million in 2021 in connection with the FDA approval in May 2021. During the nine months ended September 30, 2022, we have paid SFJ \$16.5 million which consisted of \$5.0 million in connection with the EMA approval in

December 2021 and \$11.5 million in connection with the one-year anniversary of the FDA approval, respectively. We are obligated to pay SFJ an additional \$439.5 million in the aggregate in eleven semi-annual payments with the majority of the payments being made from the third anniversary to the sixth anniversary of regulatory approval. We are obligated to pay a total of \$18.0 million to SFJ in connection with the one-year anniversary of the EMA approval.

Collaboration Agreement with Sobi

On October 27, 2020, we entered into the Sobi collaboration agreement, concerning the development and commercialization of pegcetacoplan and specified other structurally and functionally similar compstatin analogues or derivatives for use systemically or for local non-ophthalmological administration, collectively referred to as the licensed products. We granted Sobi an exclusive (subject to certain rights retained by us), sublicensable license of certain patent rights and know-how to develop and commercialize licensed products in all countries outside of the United States. We retained the right to commercialize licensed products in the United States, and, subject to specified limitations, to develop licensed products worldwide for commercialization in the United States. Under the Sobi collaboration agreement, Sobi made an upfront payment of \$250.0 million in November 2020, and agreed to pay up to an aggregate of \$915.0 million upon the achievement of specified one-time regulatory and commercial milestone events, including a \$50.0 million milestone which would be payable following the first regulatory and reimbursement approval of system pegcetacoplan in any major European country, and to reimburse us for up to \$80.0 million in development costs. In January 2021 we received a \$25.0 million development reimbursement payment from Sobi and in January 2022 we received a \$20.0 million development reimbursement payment. We expect to receive the balance annually in installments over the next two years, subject to certain conditions.

European Commission approval of systemic pegcetacoplan for the treatment of PNH was received in December 2021. In March 2022, we earned a \$50.0 million payment from Sobi related to the first regulatory and reimbursement milestone in Europe. We considered the reimbursement approval to be probable at December 31, 2021, and recorded revenue at that time. We received the \$50.0 million payment in April 2022. We are also entitled to receive tiered, double-digit royalties (ranging from high teens to high twenties) on sales of licensed products outside of the United States, subject to customary deductions and third-party payment obligations, until the latest to occur of: (i) expiration of the last-to-expire of specified licensed patent rights; (ii) expiration of regulatory exclusivity; and (iii) ten (10) years after the first commercial sale of the applicable licensed product, in each case on a licensed product-by-licensed product and country-by-country basis. We remain responsible for our license fee obligations (including royalty obligations) to the University of Pennsylvania and for our payment obligations to SFJ.

Financial Operations Overview

Revenue

Our revenues consist of product sales of EMPAVELI, and revenues derived from our collaboration arrangement with Sobi.

Revenue is recognized when, or as, we satisfy a performance obligation by transferring a promised good or service to a customer. An asset is transferred when, or as, the customer obtains control of that asset. For performance obligations that are satisfied over time, we recognize revenue using an input or output measure of progress that best depicts the satisfaction of the relevant performance obligation.

Product Revenues

Product revenue is derived from our sales of our commercial product, EMPAVELI, in the United States.

Licensing and Other Revenue

Licensing and other revenue is derived from our collaboration agreement with Sobi concerning the development and commercialization of pegcetacoplan and specified other compstatin analogues or derivatives for use systemically or for local non-ophthalmic administration.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our product candidates, which include:

- employee-related expenses including salaries, bonuses, benefits and share-based compensation expense related to individuals performing research and development activities;

- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct clinical trials and research and development activities on our behalf, and contract manufacturing organizations that manufacture quantities of drug supplies for both our preclinical studies and clinical trials;
- the cost of consultants, including share-based compensation expense; and
- various other expenses incident to the management of our preclinical studies and clinical trials.

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed. We have not provided program costs since inception because historically we have not tracked or recorded our research and development expenses on a program-by-program basis.

The successful development of our product candidates in clinical development is highly uncertain. Accordingly, at this time, we cannot reasonably estimate the nature, timing and costs of the efforts that will be necessary to complete the remainder of the clinical development of these product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from pegcetacoplan in other jurisdictions and indications or any other potential product candidates. This is due to the numerous risks and uncertainties associated with developing therapeutics, including the uncertainties of:

- establishing an appropriate safety profile in preclinical studies;
- successful enrollment in, and completion of clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others; and
- an acceptable safety profile of the products following approval.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs and timing associated with the development of that product candidate.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase for the foreseeable future as our product candidate development programs progress. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses including salaries, bonuses, benefits and share-based compensation. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters, and fees for accounting and consulting services.

We anticipate that our general and administrative expenses will increase in the future to support the commercialization of EMPAVELI in PNH and, if approved, intravitreal pegcetacoplan, continued research and development activities, potential commercialization of our other product candidates and costs of operating as a public company.

Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these 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 the financial statements, as well as the reported amounts of expenses during the reported periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to product revenue, licensing revenue, costs of research collaboration arrangements, inventory, accrued research and development expenses, convertible notes, capped call

transactions and the development derivative liability and development liability, which we described in our 2021 Annual Report on Form 10-K. 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 significant accounting policies are described in Note 2 of Part I, Item 1 of this Quarterly Report on Form 10-Q and in Part I, Item 7, “Critical Accounting Policies and Estimates” in our 2021 Annual Report on Form 10-K. There have been no changes to our critical accounting policies and estimates since our 2021 Annual Report on Form 10-K.

Results of Operations

Three Months Ended September 30, 2022 and 2021 (in thousands, except percentages)

	For the Three Months Ended September 30,		Change \$	Change %
	2022	2021		
Revenue:				
Product revenue, net	\$ 17,676	\$ 5,314	\$ 12,362	233%
Licensing and other revenue	4,380	336	4,044	1204%
Total revenue:	22,056	5,650	16,406	290%
Operating expenses:				
Cost of sales	1,381	149	1,232	827%
Research and development	95,207	87,733	7,474	9%
General and administrative	78,406	45,763	32,643	71%
Total operating expenses:	174,994	133,645	41,349	31%
Net operating loss	(152,938)	(127,995)	(24,943)	19%
Loss on conversion of debt	(32,890)	(61,102)	28,212	(46%)
Loss from remeasurement of development derivative liability	—	(4,219)	4,219	(100%)
Interest income	2,809	144	2,665	1,851%
Interest expense	(7,903)	(2,282)	(5,621)	246%
Other income/(expense), net	99	(117)	216	(185%)
Net loss before taxes	(190,823)	(195,571)	4,748	(2%)
Income tax expense	446	—	446	100%
Net loss	\$ (191,269)	\$ (195,571)	\$ 4,302	(2%)

Product Revenue, Net

Our product revenue, net is derived from EMPAVELI sales in the United States which was launched in May 2021. We recognized \$17.7 million and \$5.3 million of net product revenue for the three months ended September 30, 2022 and 2021, respectively.

Licensing and Other Revenue

Licensing and other revenue of \$4.4 million for the three months ended September 30, 2022 includes \$3.6 million in revenue from product supplied to Sobi and \$0.8 million in royalty revenue from Sobi. Licensing and other revenue for the three months ended September 30, 2021 includes \$0.4 million in revenues for product supplied to Sobi.

Cost of Sales

Cost of sales was \$1.4 million for the three months ended September 30, 2022 and \$0.1 million for the three months ended September 30, 2021. The increase in cost of sales was primarily driven by an increase in product sales volume and royalty expense of \$1.1 million.

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the three months ended September 30, 2022 and 2021 (in thousands, except percentages):

	For the Three Months Ended September 30,		Change \$	Change %
	2022	2021		
Clinical trial costs	\$ 19,495	\$ 28,393	\$ (8,898)	(31 %)
Compensation and related personnel costs	40,731	28,421	12,310	43 %
Contract manufacturing	11,317	15,076	(3,759)	(25 %)
Sobi development milestone	—	(6,447)	6,447	(100 %)
Research / innovation costs	6,228	3,991	2,237	56 %
Other development costs	13,573	14,903	(1,330)	(9 %)
Pre-clinical study expenses	2,428	3,287	(859)	(26 %)
Device development expenses	1,435	109	1,326	1,217 %
Total research and development expenses	<u>\$ 95,207</u>	<u>\$ 87,733</u>	<u>\$ 7,474</u>	<u>9 %</u>

Research and development expenses increased by \$7.5 million to \$95.2 million for the three months ended September 30, 2022 from \$87.7 million for the three months ended September 30, 2021, an increase of 9.0%. The increase was primarily attributable to an increase of \$12.3 million in personnel related costs due to having more employees in the three months ended September 30, 2022, an increase of \$2.2 million in research and innovation costs, and an increase of \$1.4 million in device development expenses. In addition, we recorded no contra research and development expenses under the Sobi collaboration for the three months ended September 30, 2022 as compared to \$6.4 million for the three months ended September 30, 2021. The increases were partially offset by a decrease of \$8.9 million in clinical trial costs due to the completion of our Phase 3 DERBY and OAKS trials, a decrease of \$3.8 million in contract manufacturing expenses due primarily to the timing of drug supply and analytical activity, a decrease of \$1.3 million in other development costs, and a decrease of \$0.8 million in preclinical study expenses.

General and Administrative Expenses

General and administrative expenses increased by \$32.6 million to \$78.4 million for the three months ended September 30, 2022, from \$45.8 million for the three months ended September 30, 2021, an increase of 71%. The increase was primarily attributable to higher employee related costs of \$15.7 million, an increase in professional and consulting fees and general commercial preparation activities of \$15.1 million, higher office costs of \$1.0 million, an increase in travel related expenses of \$1.2 million, and higher insurance costs of \$0.3 million. The increase was partially offset by lower director stock option compensation of \$0.7 million. The increase in employee related costs of \$15.7 million consisted of a \$12.2 million increase in salaries and benefits primarily due to the higher number of employees in the current period, an increase of \$0.1 million in recruiting expenses, and \$3.4 million related to stock compensation expense associated with the grant of stock options and restricted stock units to employees. The increase in other professional and consulting fees and general commercial preparation activities of \$15.1 million was primarily related to higher commercialization related activity of \$16.9 million and was partially offset by a decrease in general professional fees of \$1.8 million.

Loss on Conversion of Debt

Loss on conversion of debt was \$32.9 million for the three months ended September 30, 2022. Loss on conversion of debt was \$61.1 million for the three months ended September 30, 2021. See Note 7 Long-term Debt in the Notes to Unaudited Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for additional details regarding the conversion of debt in the three months ended September 30, 2022 and 2021, respectively.

Loss from Remeasurement of Development Derivative Liability

Loss from remeasurement of development derivative liability was \$4.2 million for the three months ended September 30, 2021. On December 15, 2021, the development derivative liability was reclassified to development liability and no longer remeasured to fair value at the end of each quarter. See Note 6 Development Liability and Development Derivative Liability in the Notes to Unaudited Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for additional details regarding the development derivative liability.

Interest Income

Interest income was \$2.8 million for the three months ended September 30, 2022, an increase of \$2.7 million, compared to \$0.1 million for the three months ended September 30, 2021. The increase in interest income was primarily attributable to purchases of marketable securities and increased money market rates during the three months ended September 30, 2022.

Interest Expense

Interest expense was \$7.9 million for the three months ended September 30, 2022 and \$2.3 million for the three months ended September 30, 2021. The increase is primarily due to accretion of the development liability discount related to the SFJ agreement in the current period.

Other Income/(Expense), Net

Other income/(expense), net, increased \$0.2 million during the three months ended September 30, 2022 compared to the three months ended September 30, 2021. The increase was primarily due to an increase in other taxes and foreign currency revaluation gains.

Income Tax Expense

Income tax expense increased by \$0.4 million during the three months ended September 30, 2022 compared to the three months ended September 30, 2021. The increase primarily pertained to federal and state income taxes where the utilization of net operating losses and research and development tax credits are limited.

Nine Months Ended September 30, 2022 and 2021 (in thousands, except percentages)

	For the Nine Months Ended September 30,		Change \$	Change %
	2022	2021		
Revenue:				
Product revenue, net	\$ 45,439	\$ 5,937	\$ 39,502	665 %
Licensing and other revenue	7,320	336	6,984	2079 %
Total revenue:	52,759	6,273	46,486	741 %
Operating expenses:				
Cost of sales	2,711	149	2,562	1719 %
Research and development	287,813	267,688	20,125	8 %
Cost of research collaboration	—	50,000	(50,000)	(100 %)
General and administrative	192,795	135,309	57,486	42 %
Total operating expenses:	483,319	453,146	30,173	7 %
Net operating loss	(430,560)	(446,873)	16,313	(4 %)
Loss on conversion of debt	(32,890)	(100,589)	67,699	(67 %)
Loss from remeasurement of development derivative liability	—	(42,483)	42,483	(100 %)
Interest income	4,339	381	3,958	1039 %
Interest expense	(24,888)	(10,223)	(14,665)	143 %
Other (expense)/ income, net	(42)	1,366	(1,408)	(103 %)
Net loss before taxes	\$ (484,041)	\$ (598,421)	\$ 114,380	(19 %)
Income tax expense	2,140	—	2,140	100 %
Net loss	\$ (486,181)	\$ (598,421)	\$ 112,240	(19 %)

Product Revenue, Net

Our product revenue, net is derived from EMPAVELI sales in the United States which was launched in May 2021. We recognized \$45.4 million and \$5.9 million of net product revenue for the nine months ended September 30, 2022 and 2021.

Licensing and Other Revenue

Licensing and other revenue of \$7.3 million during the nine months ended September 30, 2022 includes \$5.7 million in revenue for product supplied to Sobi and \$1.6 million in royalty revenue. Licensing and other revenue includes \$0.4 million revenue for product supplied to Sobi during the nine months ended September 30, 2021.

Cost of Sales

Cost of sales was \$2.7 million for the nine months ended September 30, 2022 and \$0.1 million for the nine months ended September 30, 2021. The increase in cost of sales was driven by an increase in product sales volume, an increase in royalty expense of \$1.8 million and an increase in scrap.

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the nine months ended September 30, 2022 and 2021 (in thousands, except percentages):

	For the Nine Months Ended September 30,		Change \$	Change %
	2022	2021		
Clinical trial costs	\$ 68,929	\$ 89,102	\$ (20,173)	(23 %)
Compensation and related personnel costs	117,626	78,891	38,735	49 %
Contract manufacturing	34,922	60,726	(25,804)	(42 %)
Sobi development milestone	(4,993)	(23,613)	18,620	(79 %)
Research / innovation costs	15,296	13,342	1,954	15 %
Other development costs	46,122	39,621	6,501	16 %
Pre-clinical study expenses	8,209	9,314	(1,105)	(12 %)
Device development expenses	1,702	305	1,397	458 %
Research and development expenses	287,813	267,688	20,125	8 %
Cost of research collaboration	—	50,000	(50,000)	(100 %)
Total research and development expenses including cost of research collaboration	\$ 287,813	\$ 317,688	\$ (29,875)	(9 %)

Research and development expenses decreased by \$29.9 million to \$287.8 million for the nine months ended September 30, 2022 from \$317.7 million for the nine months ended September 30, 2021, a decrease of 9%. The decrease was primarily attributable to the \$50.0 million cost of research collaboration associated with the Beam arrangement recorded in the prior period, a decrease of \$25.8 million in contract manufacturing expenses due primarily to the timing of drug supply and analytical activity, a decrease of \$20.2 million in clinical trial costs due to the completion of our Phase 3 DERBY and OAKS trials, and a decrease of \$1.1 million in pre-clinical study expenses. The decrease was partially offset by a \$38.7 million increase in personnel related costs due to having more employees in the nine months ended September 30, 2022, an increase of \$2.0 million in research and innovation cost, an increase of \$1.4 million in device development expenses, and an increase of \$6.5 million in other research and development supporting activities primarily driven by regulatory, quality and medical affairs expenses. In addition, contra research and development expenses under the Sobi collaboration were \$5.0 million for the nine months ended September 30, 2022 compared to \$23.6 million for the nine months ended September 30, 2021.

General and Administrative Expenses

General and administrative expenses increased by \$57.5 million to \$192.8 million for the nine months ended September 30, 2022, from \$135.3 million for the nine months ended September 30, 2021, an increase of 42%. The increase was primarily attributable to an increase in employee related costs of \$30.2 million, an increase in professional and consulting fees and general commercial preparation activities of \$24.1 million, an increase in travel related expenses of \$3.0 million, higher office costs of \$2.0 million, and an increase in insurance costs of \$0.7 million. The increase was partially offset by lower director stock option compensation of \$2.5 million. The increase in employee related costs of \$30.2 million consisted of a \$19.6 million increase in salaries and benefits primarily due to the higher number of employees in the current period, an increase of \$8.7 million related to stock compensation expense associated with the grant of stock options and restricted stock units to employees, and an increase of \$1.9 million in recruiting expenses. The increase in other professional and consulting fees and general commercial preparation activities of \$24.1 million primarily related to higher commercialization related activity of \$27.6 million, partially offset by a decrease in general professional fees of \$3.5 million.

Loss on Conversion of Debt

Loss on conversion of debt was \$32.9 million for the nine months ended September 30, 2022. Loss on conversion of debt was \$100.6 million for the nine months ended September 30, 2021. See Note 7 Long-term Debt in the Notes to Unaudited Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for additional details regarding the conversion of debt in the nine months ended September 30, 2022 and 2021, respectively.

Loss from Remeasurement of Development Derivative Liability

Loss from remeasurement of development derivative liability was \$42.5 million for the nine months ended September 30, 2021. On December 15, 2021, the development derivative liability was reclassified to development liability and no longer remeasured to fair value at the end of each quarter. See Note 6 Development Liability and Development Derivative Liability in the Notes to Unaudited Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for additional details regarding the development derivative liability.

Interest Income

Interest income was \$4.4 million for the nine months ended September 30, 2022, an increase of \$4.0 million compared to \$0.4 million for the nine months ended September 30, 2021. The increase in interest income was primarily attributable to purchases of marketable securities and increased money market rates during the three months ended September 30, 2022.

Interest Expense

Interest expense was \$24.9 million for the nine months ended September 30, 2022 and \$10.2 million for the nine months ended September 30, 2021. The increase was primarily due to accretion of the development liability discount related to the SFJ agreement in the current period.

Other (Expense)/Income, Net

Other (expense)/income, net during the nine months ended September 30, 2022 decreased \$1.4 million compared to the nine months ended September 30, 2021. The decrease was primarily due to foreign currency revaluation losses.

Income Tax Expense

Income tax expense increased by \$2.1 million during the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021. The increase primarily pertained to federal and state income taxes where the utilization of net operating losses and research and development tax credits are limited.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have financed our operations primarily through \$1.6 billion in net proceeds from public offerings of our common stock, including our initial public offering, or IPO, \$535.8 million in net proceeds from offerings of Convertible Notes, a \$250.0 million up-front payment and a \$45.0 million development reimbursement payment from Sobi pursuant to the Sobi collaboration agreement, \$112.6 million in proceeds from the private placement of shares of our convertible preferred stock prior to our IPO, \$140.0 million under the SFJ agreement, \$20.0 million in proceeds from borrowings under a term loan facility with Silicon Valley Bank, and \$7.0 million in proceeds from our issuance and sale of a promissory note. We have repaid the term loan facility and the promissory note in full, and we exchanged \$425.4 million of aggregate principal amount of our Convertible Notes for shares of our common stock.

In April 2018, we issued and sold 5,500,000 shares of our common stock in a follow-on public offering at a public offering price of \$25.50 per share for net proceeds of \$131.2 million, after deducting underwriting discounts and commissions of \$8.4 million and offering expenses of \$0.5 million.

In March 2019, we issued and sold 6,900,000 shares of our common stock in a follow-on offering at a public offering price of \$17.00. We received net proceeds of \$109.6 million after deducting underwriting discounts and commissions of \$7.0 million and offering costs of \$0.7 million.

In September 2019, we completed a private offering of \$220.0 million aggregate principal amount of Convertible Notes, or the 2019 Convertible Notes. We received net proceeds of approximately \$212.9 million after deducting the initial purchasers' discounts and commissions and offering costs of \$7.1 million.

In January 2020, we issued and sold 10,925,000 shares of our common stock in a follow-on offering at a public offering price of \$37.00, including 1,425,000 shares sold pursuant to the underwriters' exercise in full of their option to purchase additional shares of common stock. We received total net proceeds of \$381.4 million after deducting underwriting discounts and commissions of \$22.2 million and offering costs of \$0.5 million.

In May 2020, we completed a private offering of \$300.0 million aggregate principal amount of Convertible Notes, or the 2020 Convertible Notes. We received net proceeds of approximately \$322.9 million, which included accrued interest March 15, 2020 to, but not including May 12, 2020, and the initial purchasers' discounts and commissions and offering costs of \$6.0 million.

In January 2021, we entered into separate, privately negotiated exchange agreements with certain holders of our 2019 Convertible Notes. Under the terms of these exchange agreements, the holders exchanged approximately \$126.1 million in aggregate principal amount of 2019 Convertible Notes held by them for an aggregate of 3,906,869 shares of our common stock. These exchange transactions closed in January 2021.

In July 2021, we entered into separate, privately negotiated exchange agreements to modify the conversion terms with certain holders of the Convertible Notes. Under the terms of these exchange agreements, the holders exchanged approximately \$201.1 million in aggregate principal amount of Convertible Notes held by them for an aggregate of 5,992,217 shares of common stock. These exchange transactions closed in July 2021.

In November 2021, we issued and sold 10,062,500 shares of our common stock in a follow-on offering at a public offering price of \$40.00, including 1,312,500 shares sold pursuant to the underwriters' exercise in full of their option to purchase additional shares of common stock. We received total net proceeds of \$380.4 million after deducting underwriting discounts and commissions of \$22.1 million and offering costs of \$0.6 million.

In March 2022, we issued and sold 8,563,830 shares of our common stock in a follow-on offering at a public offering price of \$47.00, including 1,117,021 shares sold pursuant to the underwriters' exercise in full of their option to purchase additional shares of common stock. We received total net proceeds of \$380.1 million after deducting underwriting discounts and commissions of \$22.1 million and offering costs of \$0.3 million.

In July 2022, we entered into separate, privately negotiated exchange agreements with certain holders of Convertible Notes pursuant to which the holders exchanged approximately \$98.1 million in aggregate principal amount of Convertible Notes held by them for an aggregate of 3,027,018 shares of common stock. These exchange transactions closed in August 2022. As of September 30, 2022, there was \$93.9 million in aggregate principal amount of Convertible Notes outstanding and held by third parties.

The capped call transactions that we entered into concurrently with the issuance of the Convertible Notes are expected generally to reduce the potential dilution to our common stock upon any conversion of the Convertible Notes and/or offset any cash payments we are required to make in excess of the principal amount of converted convertible notes, as the case may be, in the event that the market price per share of our common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which is initially \$39.4625, the conversion price of the convertible notes.

Refer to Note 7 Long-term Debt in the Notes to Unaudited Condensed Consolidated Financial Statements in Part I, Item I of this Quarterly Report on Form 10-Q for additional information regarding the convertible notes and capped call transactions.

Cash Flows

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

	For the Nine Months Ended September 30,	
	2022	2021
Net cash used in operating activities	\$ (373,001)	\$ (450,627)
Net cash (used in) investing activities	(64,236)	162,636
Net cash provided by financing activities	381,605	8,278
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(675)	(2,024)
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (56,307)</u>	<u>\$ (281,737)</u>

Net Cash Used in Operating Activities

Net cash used in operating activities was \$373.0 million for the nine months ended September 30, 2022 and consisted primarily of a net loss of \$486.2 million adjusted for \$124.4 million of non-cash items, including share-based compensation expense of \$66.8 million, a loss on early exchange of debt of \$32.9 million, the forfeiture of accrued interest in the exchange of the Convertible Notes

of \$1.3 million, depreciation expense of \$1.2 million, accretion of discount to the development liability of \$20.1 million, and other liabilities of \$1.9 million. Further, it includes a net decrease in current operating assets of \$1.5 million, an increase in other assets of \$15.9 million, a decrease in accounts payable of \$4.4 million and a decrease in accrued expenses of \$21.3 million.

Net cash used in operating activities was \$450.6 million for the nine months ended September 30, 2021 and consisted primarily of a net loss of \$598.4 million adjusted for \$200.5 million of non-cash items, including a loss on early exchange of debt of \$100.6 million and a loss from remeasurement of development derivative liability of \$42.5 million, share-based compensation expense of \$51.4 million, and the forfeiture of accrued interest in the exchange of the Convertible Notes of \$4.2 million, a net decrease in current operating assets of \$3.4 million, an increase in other assets of \$4.0 million, a decrease in accounts payable of \$3.2 million and an increase in accrued expenses of \$42.1 million.

Net Cash Used in Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2022 was \$64.2 million primarily due to \$331.9 million in purchases of marketable securities, partially offset by \$268.3 million in proceeds from maturity of marketable proceeds.

Net cash provided by investing activities during the nine months ended September 30, 2021 was \$162.6 million primarily due to \$335.0 million in proceeds from maturities of marketable securities, partially offset by 171.3 million in purchases of marketable securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$381.6 million during the nine months ended September 30, 2022 and consisted primarily of proceeds from the follow-on common stock offering in March 2022 of \$380.1 million, \$19.4 million proceeds upon the exercise of stock options and \$2.6 million proceeds from the issuance of common stock under the employee stock purchase plan partially offset by payments of \$16.5 million for the development liability as well as \$4.0 million for the payments of employee tax withholding related to equity-based compensation.

Net cash provided by financing activities was \$8.3 million during the nine months ended September 30, 2021 and consisted primarily of \$12.1 million upon the exercise of stock options and \$1.7 million sales of common stock under the employee stock purchase plan, offset by \$4.0 million for the payment on the development derivative liability as well as \$1.5 million for the payment of employee tax withholding related to equity-based compensation.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution of EMPAVELI and pre-commercialization activities related to intravitreal pegcetacoplan for GA. In addition, we expect our expenses to increase as we continue the research and development of, and seek marketing approval for, our product candidates. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or commercialization efforts.

We believe that our cash, cash equivalents and marketable securities as of September 30, 2022, along with cash anticipated to be generated from sales of EMPAVELI and from intravitreal pegcetacoplan for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD), as well as committed development reimbursement payments from Sobi, will enable us to fund our operating expenses and capital expenditure requirements at least into the first quarter of 2024. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. We are devoting resources to the building of a commercial infrastructure for intravitreal pegcetacoplan for GA. We will incur substantial additional commercialization expenses for intravitreal pegcetacoplan if we obtain regulatory approval for GA. We are also devoting additional resources to the development of our product candidates. We will need to seek additional funding to conduct these activities. Because of the numerous risks and uncertainties associated with the commercialization of EMPAVELI, the development of intravitreal pegcetacoplan and other product candidates, and because the extent to which we may enter into collaborations with third parties for the development of these product candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future funding requirements will depend on many factors, including:

- our ability to successfully commercialize and sell EMPAVELI in the United States;

- the cost of and our ability to effectively establish and maintain, the commercial infrastructure and manufacturing capabilities required to support the commercialization of EMPAVELI, systemic pegcetacoplan and intravitreal pegcetacoplan and any other products for which we receive marketing approval including product sales, medical affairs, marketing, manufacturing and distribution;
- the scope, progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for pegcetacoplan, and future product candidates;
- our ability to maintain a productive collaborative relationship with Sobi with respect to systemic pegcetacoplan, including our ability to achieve milestone payments under our agreement with Sobi;
- our ability to identify additional collaborators for any of our product candidates and the terms and timing of any collaboration agreement that we may establish for the development and any commercialization of such product candidates;
- the number and characteristics of future product candidates that we pursue and their development requirements;
- the outcome, timing and costs of clinical trials and of seeking regulatory approvals of pegcetacoplan in other jurisdictions and indications and other product candidates we may pursue
- the costs of commercialization activities for pegcetacoplan in additional indications or any of our other product candidates that receive marketing approval to the extent such costs are not the responsibility of our collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of pegcetacoplan in other jurisdictions and indications and our other product candidates;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims;
- the effect of competing technological and market developments;
- the effect of the COVID-19 pandemic on the healthcare system and the economy generally and on our clinical trials and other operations specifically;
- our ability to obtain adequate reimbursement for EMPAVELI in the United States or any other product we commercialize; and
- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We currently do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Debt financing, if available, would result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations

The disclosure of our contractual obligations and commitments is set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations" in our 2021 Annual Report on Form 10-K. See Note 14 Commitments and Contingencies in the Notes to Unaudited Condensed Consolidated Financial Statements in Part I, Item I of this Form 10-Q for a discussion of obligations and commitments.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of September 30, 2022, we had cash, cash equivalents and marketable securities of \$708.6 million, consisting primarily of money market funds and U.S. Government obligations and marketable securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio. We have the ability to hold our marketable securities until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

The term “disclosure controls and procedures,” as defined in Rules 13a-15(f) and 15d-15(e) under the Exchange Act of 1934 as amended, or the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

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 Chief Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2022.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

As a result of the COVID-19 pandemic, beginning in March 2020 certain of our employees began working remotely. We have not identified any material changes in the Company’s internal control over financial reporting as a result of these changes to the working environment. We are continually monitoring and assessing the COVID-19 situation to determine any potential impacts on the design and operating effectiveness of our internal controls over financial reporting.

PART II—OTHER INFORMATION

Item 1A. Risk Factors.

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021, which could materially affect our business, financial condition or future results. The risk factors disclosure in our Annual Report on Form 10-K for the year ended December 31, 2021 is qualified by the information that is described in this Quarterly Report on Form 10-Q. The risks described in our Annual Report on Form 10-K for the year ended December 31, 2021 are not our only risks. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
10.1	Form of Exchange Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 27, 2022).
10.2	Form of Exchange Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 2, 2022).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 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 – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL 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 (formatted as Inline XBRL and contained in Exhibit 101)

* Filed 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.

Apellis Pharmaceuticals, Inc.

Date: November 7, 2022

By: /s/ Cedric Francois
Cedric Francois
President and Chief Executive Officer
(principal executive officer)

Date: November 7, 2022

By: /s/ Timothy Sullivan
Timothy Sullivan
Chief Financial Officer and Treasurer
(principal financial officer)

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Cedric Francois, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Apellis Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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.

Date: November 7, 2022

By: /s/ Cedric Francois
Cedric Francois
Chief Executive Officer

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A), AS ADOPTED PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Timothy Sullivan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Apellis Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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.

Date: November 7, 2022

By: /s/ Timothy Sullivan

Timothy Sullivan
Chief Financial Officer and Treasurer

**CERTIFICATION 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 of Apellis Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Cedric Francois, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (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.

Date: November 7, 2022

By: /s/ Cedric Francois
Cedric Francois
President and Chief Executive Officer

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

**CERTIFICATION 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 of Apellis Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Timothy Sullivan, Chief Financial Officer and Treasurer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (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.

Date: November 7, 2022

By: /s/ Timothy Sullivan
Timothy Sullivan
Chief Financial Officer and Treasurer

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