

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 June 30, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38276

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 Accelerated filer
Non-accelerated filer Small reporting company
Emerging growth company

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

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

As of July 24, 2023, the registrant had 117,737,289 shares of common stock, \$0.0001 par value per share, outstanding.

APELLIS PHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2023

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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:

- the ongoing commercialization of EMPAVELI and SYFOVRE;
- 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 initiation, dosing of patients, enrollment and completion of these trials and of the anticipated results from these trials;
- our sales, marketing and distribution capabilities and strategies, including for the commercialization and manufacturing of EMPAVELI, SYFOVRE and any future products;
- the rate and degree of market acceptance and clinical utility of EMPAVELI, SYFOVRE and any future products;
- our ongoing review of the reported events of retinal vasculitis following SYFOVRE treatment;
- 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;
- the potential clinical benefits and attributes of our current and future product candidates we may develop and the inhibition of C3;
- our current and any future collaborations for the development and commercialization of our current and future product candidates;
- the potential benefits of any current or future collaboration, including our collaborations with Sobi and Beam Therapeutics, Inc.;
- the rate and degree of market acceptance and clinical utility of EMPAVELI, SYFOVRE and any other 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; 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, 2022, 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, 2022 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, SYFOVRE 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 in the United States for the treatment of adults with paroxysmal nocturnal hemoglobinuria, or PNH, and references to Aspaveli refer to systemic pegcetacoplan in the context of the commercially available product in the European Union 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. Unless otherwise stated or the context indicates otherwise, all references in this Quarterly Report on Form 10-Q to “SYFOVRE (pegcetacoplan injection)” and “SYFOVRE” refer to intravitreal pegcetacoplan in the context of the commercially available product for which we received approval from the United States Food and Drug Administration in February 2023 for the treatment of geographic atrophy secondary to age-related macular degeneration. 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
(Unaudited)
(Amounts in thousands, except per share amounts)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 616,259	\$ 551,801
Accounts receivable	110,913	7,727
Inventory	103,216	85,714
Prepaid assets	34,404	36,350
Restricted cash	1,085	1,273
Other current assets	26,809	36,658
Total current assets	892,686	719,523
Non-current assets:		
Right-of-use assets	16,726	18,747
Property and equipment, net	5,339	6,148
Other assets	827	15,799
Total assets	<u>\$ 915,578</u>	<u>\$ 760,217</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 27,500	\$ 37,342
Accrued expenses	97,716	95,139
Current portion of development liability	43,769	29,504
Current portion of right-of-use liabilities	5,852	5,625
Total current liabilities	174,837	167,610
Long-term liabilities:		
Long-term development liability	289,960	315,647
Convertible senior notes	92,883	92,736
Right-of-use liabilities	12,066	14,352
Other liabilities	429	—
Total liabilities	570,175	590,345
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000 shares authorized, and zero shares issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, \$0.0001 par value; 200,000 shares authorized at June 30, 2023 and December 31, 2022; 117,579 shares issued and outstanding at June 30, 2023, and 110,772 shares issued and outstanding at December 31, 2022	12	11
Additional paid-in capital	2,954,862	2,479,596
Accumulated other comprehensive loss	(796)	(875)
Accumulated deficit	(2,608,675)	(2,308,860)
Total stockholders' equity	345,403	169,872
Total liabilities and stockholders' equity	<u>\$ 915,578</u>	<u>\$ 760,217</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)

	<u>For the Three Months Ended June 30,</u>		<u>For the Six Months Ended June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Revenue:				
Product revenue, net	\$ 89,645	\$ 15,654	\$ 128,444	\$ 27,763
Licensing and other revenue	5,324	668	11,370	2,940
Total revenue:	<u>94,969</u>	<u>16,322</u>	<u>139,814</u>	<u>30,703</u>
Operating expenses:				
Cost of sales	8,379	82	16,188	1,329
Research and development	95,658	101,661	205,684	192,606
General and administrative	111,373	63,203	213,466	114,390
Total operating expenses:	<u>215,410</u>	<u>164,946</u>	<u>435,338</u>	<u>308,325</u>
Net operating loss	(120,441)	(148,624)	(295,524)	(277,622)
Interest income	6,002	1,432	11,395	1,530
Interest expense	(7,341)	(8,448)	(14,869)	(16,986)
Other (expense)/income, net	(63)	149	(341)	(140)
Net loss before taxes	(121,843)	(155,491)	(299,339)	(293,218)
Income tax expense	194	486	476	1,694
Net loss	<u>\$ (122,037)</u>	<u>\$ (155,977)</u>	<u>\$ (299,815)</u>	<u>\$ (294,912)</u>
Other comprehensive gain/(loss):				
Unrealized gain/(loss) on marketable securities	—	(766)	—	(818)
Foreign currency gain	(21)	(369)	79	(286)
Total other comprehensive income/(loss)	<u>(21)</u>	<u>(1,135)</u>	<u>79</u>	<u>(1,104)</u>
Comprehensive loss, net of tax	<u>\$ (122,058)</u>	<u>\$ (157,112)</u>	<u>\$ (299,736)</u>	<u>\$ (296,016)</u>
Net loss per common share, basic and diluted	<u>\$ (1.02)</u>	<u>\$ (1.46)</u>	<u>\$ (2.57)</u>	<u>\$ (2.88)</u>
Weighted-average number of common shares used in net loss per common share, basic and diluted	<u>119,316</u>	<u>106,630</u>	<u>116,594</u>	<u>102,349</u>

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, 2023	110,772	\$ 11	\$ 2,479,596	\$ (875)	\$ (2,308,860)	\$ 169,872
Issuance of common stock and pre-funded warrants in common stock offering	4,008	1	384,386	—	—	384,387
Issuance of common stock upon exercise of stock options	951	—	17,718	—	—	17,718
Vesting of restricted stock units, net of shares withheld for taxes	448	—	(10,999)	—	—	(10,999)
Share-based compensation expense	—	—	28,823	—	—	28,823
Unrealized gain on available-for-sale investments	—	—	—	—	—	—
Net loss	—	—	—	—	(177,778)	(177,778)
Foreign currency gain	—	—	—	100	—	100
Balance at March 31, 2023	<u>116,179</u>	<u>12</u>	<u>2,899,524</u>	<u>(775)</u>	<u>(2,486,638)</u>	<u>412,123</u>
Issuance of common stock upon exercise of stock options	1,208	—	22,334	—	—	22,334
Vesting of restricted stock units, net of shares withheld for taxes	119	—	(27)	—	—	(27)
Share-based compensation expense	—	—	29,277	—	—	29,277
Issuance of common stock to employee stock purchase plan	73	—	3,754	—	—	3,754
Unrealized loss on available-for-sale investments	—	—	—	—	—	—
Net loss	—	—	—	—	(122,037)	(122,037)
Foreign currency loss	—	—	—	(21)	—	(21)
Balance at June 30, 2023	<u>117,579</u>	<u>\$ 12</u>	<u>\$ 2,954,862</u>	<u>\$ (796)</u>	<u>\$ (2,608,675)</u>	<u>\$ 345,403</u>

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	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Outstanding Shares	Amount		Comprehensive Loss		
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

See accompanying notes to unaudited condensed consolidated financial statements

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

	For the Six Months Ended June 30,	
	2023	2022
Operating Activities		
Net loss	\$ (299,815)	\$ (294,912)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	58,101	43,303
Loss on disposal of fixed assets	19	—
Amortization of right-of-use assets	(37)	(61)
Depreciation expense	846	763
Amortization of discounts for convertible notes, net of financing costs	147	290
Accretion of discount to development liability	13,078	13,336
Other liabilities	—	1,571
Changes in operating assets and liabilities:		
Accounts receivable	(103,186)	2,584
Inventory	(17,502)	(32,134)
Prepaid assets	2,535	3,390
Other current assets	9,846	42,225
Other assets	14,977	15,757
Accounts payable	(9,849)	2,591
Accrued expenses	3,065	(17,287)
Net cash used in operating activities	(327,775)	(218,584)
Investing Activities		
Purchase of property and equipment	(631)	(477)
Purchase of available-for-sale securities	—	(331,863)
Proceeds from maturity of available-for-sale securities	—	143,320
Net cash (used in) provided by investing activities	(631)	(189,020)
Financing Activities		
Proceeds from issuance of common stock, net of issuance costs	384,387	380,120
Payments for development liability	(24,500)	(16,500)
Proceeds from exercise of stock options	40,052	8,770
Proceeds from issuance of common stock under employee share purchase plan	3,754	2,531
Payments of employee tax withholding related to equity-based compensation	(11,027)	(2,952)
Net cash provided by financing activities	392,666	371,969
Effect of exchange rate changes on cash, cash equivalents and restricted cash	9	(365)
Net increase (decrease) in cash, cash equivalents and restricted cash	64,269	(36,000)
Cash, cash equivalents and restricted cash at beginning of period	553,075	641,755
Cash, cash equivalents and restricted cash at end of period	\$ 617,344	\$ 605,755
Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets:		
Cash and cash equivalents	\$ 616,259	\$ 604,489
Restricted cash	1,085	1,266
Total cash, cash equivalents, and restricted cash	\$ 617,344	\$ 605,755
Supplemental Disclosures		
Cash paid for interest	\$ 1,643	\$ 3,360
Cash paid for income taxes	\$ 384	\$ 156

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, commercializing EMPAVELI (pegcetacoplan) for the treatment of paroxysmal nocturnal hemoglobinuria (“PNH”) and the commercializing of SYFOVRE (pegcetacoplan injection) for the treatment of geographic atrophy secondary to age-related macular degeneration (“GA”).

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. From inception to June 30, 2023, the Company has incurred cash outflows from operations, losses from operations and had an accumulated deficit of \$2.6 billion primarily as a result of expenses incurred through a combination of research and development activities related to our various product candidates and expenses supporting those activities.

As of July 31, 2023, the date of issuance of these unaudited condensed consolidated financial statements, the Company believes that its cash and cash equivalents of \$616.3 million as of June 30, 2023 combined with its cash flows generated from sales 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 achieve commercial success for SYFOVRE and EMPAVELI. 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, 2022 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 six months ended June 30, 2023 are

not necessarily indicative of the results to be expected for the year ending December 31, 2023 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, 2022 included in the Company's Annual Report on Form 10-K filed with the SEC on February 21, 2023 (the "2022 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 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 2022 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 2022 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 and approval for the sale of SYFOVRE in the United States in February 2023. The Company's product revenues, net of sales discounts and allowances and reserves, for the three months ended June 30, 2023 and 2022 were \$89.6 million and \$15.7 million, respectively. The Company's product revenues, net of sales discounts and allowances and reserves, for the six months ended June 30, 2023 and 2022 were \$128.4 million and \$27.8 million, respectively. The Company's product revenues consist of sales of EMPAVELI and SYFOVRE to specialty pharmacies and specialty distributors.

The table reflects product revenue by major source for the following periods (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Products:				
EMPAVELI	\$ 22,303	\$ 15,654	\$ 42,742	\$ 27,763
SYFOVRE	67,342	—	85,702	—
Total Product revenue, net	<u>\$ 89,645</u>	<u>\$ 15,654</u>	<u>\$ 128,444</u>	<u>\$ 27,763</u>

The Company's accounts receivable balance of \$110.9 million as of June 30, 2023 and \$7.7 million as of December 31, 2022, consisted of EMPAVELI and SYFOVRE product sales receivable and licensing and other revenue receivables from our collaboration with Sobi. The Company does not have a reserve related to expected credit losses against its receivable balance.

The Company's product sales reserves totaled \$10.4 million and \$2.4 million as of June 30, 2023 and December 31, 2022, respectively. These amounts are included in accrued expenses on the Company's unaudited condensed consolidated balance sheet.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the three and six months ended June 30, 2023 (in thousands):

	Chargebacks, Discounts, and Fees	Government and other rebates	Returns	Total
Ending balance at December 31, 2022	\$ 164	\$ 1,936	\$ 251	2,351
Provision related to sales in the current year	1,466	2,566	651	4,683
Adjustments related to prior period sales	—	(2)	(249)	(251)
Credits and payments made	(184)	(1,639)	—	(1,823)
Ending balance at March 31, 2023	\$ 1,446	\$ 2,861	\$ 653	\$ 4,960
Provision related to sales in the current year	3,944	5,114	1,588	10,646
Adjustments related to prior period sales	(84)	30	(416)	(470)
Credits and payments made	(1,668)	(2,946)	(141)	(4,755)
Ending balance at June 30, 2023	\$ 3,638	\$ 5,059	\$ 1,684	\$ 10,381

Significant customers - Gross product revenues and product sales receivable from the Company's customers who individually accounted for 10% of more of total gross product revenues and/or 10% or more of total product sales receivable consisted of the following:

	Percent of Total Gross Product Revenues					
	Three Months Ended June 30,			Six Months Ended June 30,		
	2023	2022		2023	2022	
Customer A	24 %	99 %		33 %	99 %	
Customer C	13 %	—		12 %	—	
Customer D	58 %	—		50 %	—	

	Percent of Product Sales Receivable			
	As of June 30,			
	2023		2022	
Customer A	8 %		99 %	
Customer C	16 %		—	
Customer D	69 %		—	

4. Inventory

The Company's inventory consisted of the following as of June 30, 2023, and December 31, 2022 (in thousands):

	June 30, 2023	December 31, 2022
Raw materials	\$ 32,711	\$ 29,847
Semi-finished goods	48,368	54,101
Finished goods	22,137	1,766
Total Inventories	\$ 103,216	\$ 85,714

5. Prepaid and Other Current Assets

Prepaid and other current assets consisted of the following as of June 30, 2023, and December 31, 2022 (in thousands):

	June 30, 2023	December 31, 2022
Down payments for inventory	\$ 3,644	\$ 13,987
Prepaid research and development	18,964	15,181
Other prepaid expenses	11,796	7,182
Total prepaid expenses	\$ 34,404	\$ 36,350

	June 30, 2023	December 31, 2022
Royalties receivable	\$ 2,386	\$ 1,442
ERC credit	—	8,711
Receivable from collaboration agreement	15,000	20,000
Deposits and other current assets	9,423	6,505
Total other current assets	<u>\$ 26,809</u>	<u>\$ 36,658</u>

Under the provisions of the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) signed into law on March 27, 2020 and the subsequent extension of the CARES Act, the Company was eligible for a refundable employee retention credit (“ERC”) subject to certain criteria. The ERC provides eligible employers with less than 500 employees a refundable tax credit against the employer’s share of social security taxes. The ERC is equal to 70% of qualified wages paid to employees during 2021 calendar year for a maximum credit of \$7,000 per employee for each calendar quarter through September 30, 2021. In November 2022, the Company filed for an \$8.7 million refund under the CARES Act relating to the ERC. The full refund amount was received in the current period.

6. Development 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 SFJ agreement, (such amendment, 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 in May 2021 for the use of systemic pegcetacoplan as a treatment for PNH, the Company became 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 paid SFJ the initial payment of \$4.0 million in June 2021, its first annual payment of \$11.5 million in May 2022 and its second annual payment of \$24.5 million in May 2023. The subsequent annual payments remaining are due and payable in May of each year from 2024 through 2027.

Following regulatory approval of systemic pegcetacoplan by the European Medicines Agency (“EMA”) in December 2021, the Company became 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 paid SFJ the initial payment of \$5.0 million in January 2022 and the first annual payment of \$18.0 million in December 2022. The subsequent annual payments are due and payable in December of each year from 2023 through 2027.

The Company has paid SFJ a total of \$63.0 million as of June 30, 2023.

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.

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 the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“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):

	June 30, 2023	December 31, 2022	Effective Interest Rate
Development liability	\$ 397,000	\$ 421,500	7.91 %
Less: Unamortized discount to development liability	(63,271)	(76,349)	
Less: Current portion of development liability, net of discount	(43,769)	(29,504)	
Total long term development liability	<u>\$ 289,960</u>	<u>\$ 315,647</u>	

For the three and six months ended June 30, 2023, interest expense of \$6.5 million and \$13.1 million, respectively, was recorded for the accretion of the development liability.

Future minimum SFJ payments as of June 30, 2023 are as follows (in thousands):

2023	\$ 31,000
2024	98,750
2025	103,000
2026	109,000
2027	55,250
Total future minimum payments	<u>\$ 397,000</u>

7. Accrued Expenses

Accrued expenses consisted of the following as of June 30, 2023 and December 31, 2022, (in thousands):

	June 30, 2023	December 31, 2022
Accrued research and development	\$ 31,240	\$ 34,849
Accrued royalties	3,357	907
Accrued payroll liabilities	39,744	43,212
Other	23,375	16,171
Total	<u>\$ 97,716</u>	<u>\$ 95,139</u>

8. 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. 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 million 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 Accounting Standards Update 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 exchange 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 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.

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 triggered as of March 31, 2023, and as a result the Convertible Notes were convertible at the option of the holders until June 30, 2023. No Convertible Notes were converted during this period.

The conditional conversion feature of the Convertible Notes was triggered as of June 30, 2023, and as a result the Convertible Notes became convertible at the option of the holders until September 30, 2023. Through the date of issuance of these financial statements, no Convertible Notes were converted.

As of June 30, 2023, the Company held in treasury Convertible Notes in principal amount of \$425.4 million which notes had not been cancelled.

The outstanding balance of the Convertible Notes as of June 30, 2023 and December 31, 2022 consisted of the following (in thousands):

Liability	June 30,	December 31,
	2023	2022
Principal	93,897	93,897
Less: debt discount and issuance costs, net	(1,014)	(1,161)
Net carrying amount	\$ 92,883	\$ 92,736

The following table sets forth total interest expense recognized related to the Convertible Notes during the three and six months ended June 30, 2023 and 2022 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Amortization of debt issuance costs	\$ 74	\$ 145	\$ 147	\$ 290
Contractual interest expense	822	1,680	1,643	3,360
Total interest expense	\$ 896	\$ 1,825	\$ 1,790	\$ 3,650

Future minimum payments on Convertible Notes payable as of June 30, 2023 are as follows (in thousands):

2023	\$ 1,644
2024	3,286
2025	3,286
2026	96,225
Total future minimum payments	104,441
Less: interest	(10,544)
Less: debt discount and issuance costs, net	(1,014)
Less: current portion	—
Convertible senior notes	\$ 92,883

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, 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.

9. 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 June 30, 2023 and December 31, 2022, 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):

	June 30, 2023	December 31, 2022
Operating Lease Assets	\$ 16,726	\$ 18,747
Operating Lease Liabilities	\$ 17,918	\$ 19,977
Weighted Average Remaining Term in years	3.12	3.57
Weighted Average discount rate used to measure outstanding lease liabilities	7.21 %	7.26 %

For the three months ended June 30, 2023 and 2022, the total lease cost for operating lease expense was \$1.7 million and \$1.5 million, respectively. For the six months ended June 30, 2023 and 2022, the total lease cost for operating lease expense was \$3.4 million and \$2.9 million, respectively.

Supplemental cash flow information related to operating leases for the six months ended June 30 2023 and 2022 is as follows (in thousands):

	2023	2022
Operating cash flows from operating leases	\$ 4,094	\$ 3,532
Operating lease assets obtained in exchange for lease obligations	\$ —	\$ —

The maturities of the Company's operating lease liabilities as of June 30, 2023 are as follows (in thousands):

2023	3,528
2024	6,416
2025	5,253
2026	4,339
2027 and thereafter	556
Total future minimum lease payments	20,092
Less Imputed interest	(2,174)
Total operating lease liabilities	\$ 17,918

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 six months ended June 30, 2023 and 2022 (in thousands):

	Unrealized Gains (Losses) from Marketable Securities	Foreign Currency Translation Adjustment	Unrealized Gains (Losses) from Pension Plan	Total Accumulated Other Comprehensive Income (Loss)
Balances, December 31, 2022	—	\$ (2,521)	\$ 1,646	\$ (875)
Net other comprehensive income (loss)	—	100	—	100
Balances, March 31, 2023	—	(2,421)	1,646	(775)
Net other comprehensive loss	—	(21)	—	(21)
Balances, June 30, 2023	—	(2,442)	1,646	(796)

	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	<u>(817)</u>	<u>(2,377)</u>	<u>(3,194)</u>

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):

		June 30, 2023			
Balance Sheet Classification	Type of Instrument	Level 1	Level 2	Level 3	Total
Financial Assets:					
Cash and cash equivalents:	Money market funds	\$ 454,793	\$ —	\$ —	\$ 454,793
Total Financial Assets		<u>\$ 454,793</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 454,793</u>
		December 31, 2022			
Balance Sheet Classification	Type of Instrument	Level 1	Level 2	Level 3	Total
Financial Assets:					
Cash and cash equivalents	Money market funds	\$ 527,728	\$ —	\$ —	\$ 527,728
Total Financial Assets		<u>\$ 527,728</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 527,728</u>

The Company’s Convertible Notes and development liability are financial instruments that are reported in the financial statements at historical cost. The Convertible Notes are Level 1 within the fair value level hierarchy as of June 30, 2023 and December 31, 2022. The fair value of the Convertible Notes was \$218.9 million as of June 30, 2023 and \$143.9 million as of December 31, 2022. 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 June 30, 2023 and December 31, 2022.

The fair value of the development liability was \$317.0 million and \$315.8 million as of June 30, 2022 and December 31, 2022, 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 six months ended June 30, 2023, the Company recorded \$0.2 million and \$0.5 million of income tax expense, respectively, primarily pertaining to state and foreign income taxes.

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 June 30, 2023.

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 has not recorded any amounts for unrecognized tax benefits for the period ended June 30, 2023. 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, CAD, HSCT-TMA, C3G, and IC-MPGN, 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 Sobi 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 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, \$20.0 million in January 2022 and \$20.0 million in January 2023. The remaining \$15.0 million is due from Sobi in January 2024. 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 Trustees of the University of Pennsylvania (“Penn”), 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 \$2.4 million and \$4.0 million of royalty revenue for the three and six months ended June 30, 2023, 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 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 six months ended June 30, 2023, the Company recognized \$2.4 million and \$4.0 million, respectively, of royalty revenue. For the three and six months ended June 30, 2022, the Company recognized \$0.7 million and \$0.8 million, respectively, of royalty revenue. For the three and six months ended June 30, 2023, the Company did not recognize any contra-research and development expense in the unaudited condensed consolidated statement of operations related to the \$80.0 million reimbursement commitment from Sobi. For the six months ended June 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 June 30, 2022.

As of June 30, 2023, the Company recorded \$15.0 million in current assets, which represents the receivable for contra-research and development expenses incurred but not yet reimbursed from Sobi.

As of December 31, 2022, the Company recorded a receivable of \$35.0 million, with \$20.0 million in other current assets and \$15.0 million in other assets on the consolidated balance sheet. The total receivable balance as of December 31, 2022 is for contra-research and development expenses incurred but not yet reimbursed from Sobi. The Company received the \$20.0 million recorded in other current assets in January 2023.

University of Pennsylvania License Agreement

The Company is a party to a license agreement with 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, net of a credit for the annual license maintenance payment. In June 2022, the Company paid an additional \$5.0 million to Penn upon the achievement of a development milestone, which was recognized in accrued expenses of December 31, 2021, as it was considered probable at that time. In January 2023, the Company paid \$1.0 million to Penn upon the achievement of a sales milestone for EMPAVELI in 2022. In April 2023, the Company paid \$2.3 million for the achievement of a regulatory milestone as a result of the FDA approval of SYFOVRE in February 2023.

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 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., 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 June 30, 2023, the Company is obligated to pay up to an aggregate of \$147.2 million to these vendors. In addition, the Company has other non-cancelable purchase agreements as of June 30, 2023, under which it is obligated to pay up to \$21.7 million to vendors.

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

Basic and diluted net loss per share is calculated based upon the weighted average number of shares of common stock outstanding during the period. Shares of the Company's common stock underlying pre-funded warrants are included in the calculation of basic and diluted earnings 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 June 30,	
	2023	2022
Convertible notes	2,379	4,865
Common stock options	10,665	13,072
Restricted stock units	4,669	3,254
Total	17,713	21,191

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, 2022 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 21, 2023, which we refer to as the 2022 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 2022 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 diseases with high unmet need and that are driven by excessive complement activation.

In February 2023, the U.S. Food and Drug Administration, or the FDA, approved SYFOVRE (pegcetacoplan injection), the first and only approved treatment for geographic atrophy secondary to age-related macular degeneration, or GA. We believe SYFOVRE has the potential to be a best-in-class treatment for patients with GA, a disease that affects more than one million people in the United States and five million people worldwide. We launched SYFOVRE in the United States in March 2023. For the three and six months ended June 30, 2023, we generated \$67.3 million and \$85.7 million, respectively, in net product revenue from sales of SYFOVRE.

In December 2022, we also submitted a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, for intravitreal pegcetacoplan for the treatment of GA. The EMA subsequently provided MAA validation and the application is under review and we expect a decision in early 2024. Additionally, we received validation of our marketing applications by regulatory authorities in Canada, Australia, the United Kingdom, and Switzerland for the treatment of GA and expect decisions by local regulatory authorities in the first half of 2024. We have exclusive, worldwide commercialization rights for intravitreal pegcetacoplan.

In May 2021, the FDA approved EMPAVELI (pegcetacoplan), the first targeted C3 therapy 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. For the three and six months ended June 30, 2023, we generated \$22.3 million and \$42.7 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 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 four indications in addition to PNH. Sobi is leading the development of systemic pegcetacoplan in cold agglutinin disease, or CAD, and hematopoietic stem cell transplantation-associated thrombotic microangiopathy, or HSCT-TMA, in hematology. We are leading the development of systemic pegcetacoplan in C3 glomerulopathy, or C3G, and immune complex membranoproliferative glomerulonephritis, or IC-MPGN, in nephrology. We are also evaluating the administration of systemic pegcetacoplan as a novel approach to enabling adeno associated virus, or AAV, vector administration for gene therapies.

In May 2023, we and Sobi announced that the Phase 2 MERIDIAN study evaluating systemic pegcetacoplan for amyotrophic lateral sclerosis, or ALS, did not meet its primary or key secondary endpoints. Based on this lack of efficacy, we and Sobi discontinued development of systemic pegcetacoplan for ALS. Systemic pegcetacoplan was well tolerated in the trial, and the safety data were consistent with the established safety profile.

Lastly, we are developing additional product candidates with other routes of administration and plan to advance these product candidates into clinical development in 2023. These candidates include an oral alternative pathway inhibitor for certain renal conditions. We submitted an investigational new drug application, or IND, for APL-3007, a small interfering RNA, or siRNA, in March 2023 and dosed the first subject in a Phase 1 clinical trial in June 2023. 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.

In July 2023, we disclosed that we had confirmed seven events of retinal vasculitis and were evaluating one reported event of retinal vasculitis following SYFOVRE treatment. We are working with the retinal community to investigate potential contributing factors. We will continue to submit all adverse events reported to us to the FDA consistent with reporting guidelines for drug manufacturers.

We have been conducting a thorough evaluation following these reported events, including a review of the SYFOVRE manufacturing process and drug product quality and of the safety data from our Phase 3 clinical trials of SYFOVRE. Based on this review, we have seen no indications of drug product or manufacturing issues that contributed to these events, and there were no new safety findings in the clinical trials upon secondary review. The rate of intraocular inflammation was 0.26% among all SYFOVRE-treated patients in the Phase 3 program, with zero events of retinal vasculitis observed, following more than 23,000 injections.

In July 2023, we disclosed data from GALE, our long-term extension trial of SYFOVRE. Patients receiving monthly treatment showed reduced lesion growth by 39% ($p < 0.0001$) between months 24 and 30 and patients receiving every-other-month treatment showed reduced lesion growth by 32% ($p < 0.0001$) between months 24 and 30, compared to the projected sham arm. Patients with nonsubfoveal GA lesions showed 45% ($p < 0.0001$) and 33% ($p = 0.0023$) reduced lesion growth in the monthly and every-other-month treatment arms between months 24 and 30, respectively, compared to the projected sham arm. The safety profile of SYFOVRE in the GALE study continued to be consistent with previously reported Phase 3 data.

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 June 30, 2023, we had cash and cash equivalents of \$616.3 million. We believe that our cash and cash equivalents, along with cash anticipated to be generated from sales of EMPAVELI and SYFOVRE and the remaining committed development reimbursement payment from Sobi, will be sufficient to enable us to fund our current operations into the first quarter of 2025. 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. In particular, we are assessing the impact of the reported safety events with SYFOVRE on our assumptions regarding future revenues. For additional information see "Liquidity and Capital Resources" elsewhere in this Quarterly Report on Form 10-Q.

Since the launch of EMPAVELI in May 2021 and SYFOVRE in March 2023, through June 30, 2023 we have generated \$208.6 million of net product revenue from sales of EMPAVELI and SYFOVRE. We have incurred significant annual net operating losses in every year since our inception. We expect to continue to incur net operating losses for at least this year and next year. Our net losses were \$122.0 million and \$156.0 million for the three months ended June 30, 2023 and 2022, respectively, and \$299.8 million and \$294.9 million for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of \$2.6 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 sales, marketing, medical affairs, manufacturing, distribution and other commercial infrastructure associated with the commercialization of EMPAVELI for the treatment of PNH and the commercialization of SYFOVRE for the treatment of GA. 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.

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 and \$5.0 million in January 2022 in connection with the EMA approval in December 2021. In addition, we paid \$11.5 million in connection with the one-year anniversary of the FDA approval in May 2022 and \$18.0 million in connection with the one-year anniversary of the EMA approval in December 2022 and \$24.5 million in connection with the two year anniversary of FDA approval in May 2023. We are obligated to pay SFJ an additional \$31.0 million during 2023, with additional payments due on each anniversary of FDA and EMA regulatory approval through 2027.

Convertible Notes

On September 16, 2019, we completed a private offering of convertible notes, or the 2019 Convertible Notes, with an aggregate principal amount of \$220.0 million issued pursuant to an indenture, or 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. We 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, we issued convertible notes, or 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. We 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 our senior unsecured obligations 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 our common stock at an initial conversion rate of 25.3405 shares per \$1,000 principal amount of 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 we deliver a notice of redemption, we 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 our 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 our common stock and the conversion rate on each such trading day;
- if we call 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, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of common stock, at our election.

Prior to September 20, 2023, we may not redeem the Convertible Notes. We may redeem for cash all or a portion of the Convertible Notes, at our option, on or after September 20, 2023 if the last reported sale price of our 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 we provide a notice of redemption, during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide 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 we undergo a “fundamental change,” as defined in the Indenture, prior to maturity, subject to certain conditions, holders may require us 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.

We used an effective interest rate of 10.5% to determine the liability component of the 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, we adopted ASU 2020-06 using the modified retrospective method. Upon adoption, we 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, we entered into separate, privately negotiated exchange agreements to modify the conversion terms with certain holders of our 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 we issued. In accordance with FASB ASC Topic 470-20, “Debt – Debt with Conversion and Other Options,” or ASC 470-20, we 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. We 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, we 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. We 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, we issued 69,491 shares as settlement of debt issuance costs paid to our financial advisor in connection with the exchange transaction. For the three months ended March 31, 2021, we 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 we charged to interest expense and to equity.

As a result of the July 2021 exchange transactions, we 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. We 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, we issued 78,419 shares as settlement of issuance costs paid to our financial advisor in connection with the exchange transaction. For the three months ended September 30, 2021, we 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 we charged to interest expense and to equity.

As a result of the July 2022 exchange transactions, we 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 Notes exchanged of \$98.1 million less the \$1.3 million of remaining debt issuance costs associated with the exchanged notes. We 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, we issued 46,132 shares as settlement of issuance costs paid to our financial advisor in connection with the exchange transaction. For the three months ended September 30, 2022, we 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.

A 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 March 31, 2023 and as a result the Convertible Notes were convertible at the option of the holders until September 30, 2021. During this period, no Convertible Notes were converted.

The conditional conversion feature of the Convertible Notes was again triggered as of June 30, 2023, and as a result the Convertible Notes became convertible at the option of the holders until September 30, 2023. Through the date of issuance of these financial statements, no Convertible Notes were converted.

As of June 30, 2023, we held in treasury Convertible Notes in principal amount of \$425.4 million which notes had not been cancelled.

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 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 systemic pegcetacoplan in any major European

country, and to reimburse us for up to \$80.0 million in development costs. In January 2021, January 2022 and January 2023, we received a \$25.0 million, \$20.0 million and \$20.0 million development reimbursement payment from Sobi, respectively. The remaining \$15.0 million is due from Sobi in January 2024.

We received EC approval of systemic Aspaveli (pegcetacoplan) for the treatment of adults with PNH 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 SYFOVRE, and revenues derived from our collaboration agreement 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 products, EMPAVELI and SYFOVRE, 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.

Cost of Sales

Cost of sales consists primarily of costs associated with the manufacturing of EMPAVELI and SYFOVRE, royalties owed to our licensor for such sales, and certain period costs.

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.

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 continued research and development activities, potential commercialization of our 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 and development liability, which we described in our 2022 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 2022 Annual Report on Form 10-K. There have been no changes to our critical accounting policies and estimates since our 2022 Annual Report on Form 10-K.

Results of Operations

Three Months Ended June 30, 2023 and 2022 (in thousands, except percentages)

	For the Three Months Ended June 30,		Change \$	Change %
	2023	2022		
Revenue:				
Product revenue, net	\$ 89,645	\$ 15,654	\$ 73,991	473 %
Licensing and other revenue	5,324	668	4,656	697 %
Total revenue:	94,969	16,322	78,647	482 %
Operating expenses:				
Cost of sales	8,379	82	8,297	10,118 %
Research and development	95,658	101,661	(6,003)	(6 %)
General and administrative	111,373	63,203	48,170	76 %
Total operating expenses:	215,410	164,946	50,464	31 %
Net operating loss	(120,441)	(148,624)	28,183	(19 %)
Interest income	6,002	1,432	4,570	319 %
Interest expense	(7,341)	(8,448)	1,107	(13 %)
Other (expense)/income, net	(63)	149	(212)	(142 %)
Net loss before taxes	(121,843)	(155,491)	33,648	(22 %)
Income tax expense	194	486	(292)	(60 %)
Net loss	<u>\$ (122,037)</u>	<u>\$ (155,977)</u>	<u>\$ 33,940</u>	(22 %)

Product Revenue, Net

Our product revenue, net is derived from EMPAVELI sales in the United States and SYFOVRE sales in the United States. We recognized \$89.6 million and \$15.7 million of net product revenue for the three months ended June 30, 2023 and 2022, respectively. The net product revenue of \$89.6 million for the three months ended June 30, 2023, consists of \$22.3 million in net product revenue from sales of EMPAVELI and \$67.3 million in net product revenue from sales of SYFOVRE.

Licensing and Other Revenue

Licensing and other revenue of \$5.3 million for the three months ended June 30, 2023 consisted of \$2.9 million in revenue from product supplied to Sobi and \$2.4 million in royalty revenue from Sobi. Licensing and other revenue of \$0.7 million three months ended June 30, 2022 consisted of \$0.7 million in royalty revenue from Sobi.

Cost of Sales

Cost of sales was \$8.4 million for the three months ended June 30, 2023 and \$0.1 million for the three months ended June 30, 2022. The increase in cost of sales was primarily driven by a \$1.7 million increase due to increased product volume from commercial sales and product provided under our patient assistance programs, a \$3.3 million increase from cost of supply provided under the Sobi collaboration agreement, a \$2.7 million increase in royalty expense, and a \$0.6 million increase in expenses incurred related to excess or obsolete inventory.

In addition, prior to receiving FDA approval for EMPAVELI and SYFOVRE, the costs associated with the manufacturing of EMPAVELI and SYFOVRE inventory were expensed as incurred as research and development expense. This resulted in inventory being sold for the three months ended June 30, 2023 and 2022 for which a portion of the costs had been previously expensed prior to FDA approval. We expect this to continue to impact the cost of sales as the remaining pre-FDA approval inventory is sold to customers.

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the three months ended June 30, 2023 and 2022 (in thousands, except percentages):

	For the Three Months Ended June 30,		Change \$	Change %
	2023	2022		
Clinical trial costs	\$ 21,312	\$ 22,636	\$ (1,324)	(6%)
Compensation and related personnel costs	47,545	39,136	8,409	21%
Contract manufacturing	140	13,278	(13,138)	(99%)
Research/innovation costs	6,118	5,086	1,032	20%
Other development costs	17,503	17,452	51	0%
Pre-clinical study expenses	2,255	3,916	(1,661)	(42%)
Device development expenses	785	157	628	400%
Total research and development expenses	\$ 95,658	\$ 101,661	\$ (6,003)	(6%)

Research and development expenses decreased by \$6.0 million to \$95.7 million for the three months ended June 30, 2023 from \$101.7 million for the three months ended June 30, 2022, a decrease of 6%. The decrease was primarily attributable to a decrease of \$13.1 million in contract manufacturing expenses due primarily to the timing of drug supply and analytical activity, a decrease of \$1.3 million in clinical trial costs due to the completion of our Phase 3 DERBY and OAKS trials, and a decrease of \$1.6 million in preclinical study expenses. The decrease was partially offset by a \$8.4 million increase in personnel related costs due to having more employees in the three months ended June 30, 2023, an increase of \$1.0 million in research and innovation costs, and an increase of \$0.6 million in device development expenses.

General and Administrative Expenses

General and administrative expenses increased by \$48.2 million to \$111.4 million for the three months ended June 30, 2023, from \$63.2 million for the three months ended June 30, 2022, an increase of 76%. The increase was primarily attributable to an increase in personnel related costs of \$22.1 million, an increase in professional and consulting fees and general commercial preparation activities of \$24.5 million, an increase in travel related expenses of \$0.5 million, higher office costs of \$0.9 million, and an increase in director stock option compensation of \$0.2 million. The increase in personnel related costs of \$22.1 million consisted of a \$16.4 million increase in salaries and benefits primarily due to having more employees in the three months ended June 30, 2023, an increase of \$7.0 million related to stock compensation expense associated with the grant of stock options and restricted stock units to employees, partially offset by a decrease of \$1.3 million in recruiting expenses. The increase in other professional and consulting fees and general commercial preparation activities of \$24.5 million consisted primarily of higher commercialization related activity of \$21.2 million, and an increase in general professional fees of \$3.3 million.

Interest Income

Interest income was \$6.0 million for the three months ended June 30, 2023, an increase of \$4.6 million, compared to \$1.4 million for the three months ended June 30, 2022. The increase in interest income was primarily attributable to increased money market interest rates during the three months ended June 30, 2023.

Interest Expense

Interest expense was \$7.3 million for the three months ended June 30, 2023, a decrease of \$1.1 million, compared to \$8.4 million for the three months ended June 30, 2022. The decrease is primarily due to lower outstanding principal amount of the Convertible Notes.

Other (Expense)/Income, Net

Other expense was \$0.1 million, for the three months ended June 30, 2023, as compared to other income of \$0.1 million for the three months ended June 30, 2022. Other expense increase was primarily due to foreign currency revaluation losses.

Income Tax Expense

Income tax expense was \$0.2 million for the three months ended June 30, 2023, decrease of \$0.3 million, compared to \$0.5 million for the three months ended June 30, 2022. The decrease primarily pertained to a decrease in U.S. taxable income, driven in part by lower research and development capitalization.

Six Months Ended June 30, 2023 and 2022 (in thousands, except percentages)

	For the Six Months Ended June 30,		Change \$	Change %
	2023	2022		
Revenue:				
Product revenue, net	\$ 128,444	\$ 27,763	\$ 100,681	363 %
Licensing and other revenue	11,370	2,940	8,430	287 %
Total revenue:	139,814	30,703	109,111	355 %
Operating expenses:				
Cost of sales	16,188	1,329	14,859	1,118 %
Research and development	205,684	192,606	13,078	7 %
General and administrative	213,466	114,390	99,076	87 %
Total operating expenses:	435,338	308,325	127,013	41 %
Net operating loss	(295,524)	(277,622)	(17,902)	6 %
Interest income	11,395	1,530	9,865	645 %
Interest expense	(14,869)	(16,986)	2,117	(12 %)
Other (expense)/income, net	(341)	(140)	(201)	144 %
Net loss before taxes	\$ (299,339)	\$ (293,218)	\$ (6,121)	2 %
Income tax expense	476	1,694	(1,218)	(72 %)
Net loss	\$ (299,815)	\$ (294,912)	\$ (4,903)	2 %

Product Revenue, Net

Our product revenue, net is derived from EMPAVELI sales in the United States which was launched in May 2021 and SYFOVRE sales in the United States which was launched in March 2023. We recognized \$128.4 million and \$27.7 million of net product revenue for the six months ended June 30, 2023 and 2022, respectively. The net product revenue of \$128.4 million for the six months ended June 30, 2023, consisted of \$42.7 million in net product revenue from sales of EMPAVELI and \$85.7 million in net product revenue from sales of SYFOVRE.

Licensing and Other Revenue

Licensing and other revenue of \$11.4 million during the six months ended June 30, 2023 included \$7.4 million in revenue for product supplied to Sobi and \$4.0 million in royalty revenue from Sobi. Licensing and other revenue of \$2.9 million during the six months ended June 30, 2022 included \$2.1 million in revenue for product supplied to Sobi and \$0.8 million in royalty revenue from Sobi.

Cost of Sales

Cost of sales was \$16.2 million for the six months ended June 30, 2023 and \$1.3 million for the six months ended June 30, 2022. The increase in cost of sales was primarily driven by a \$2.7 million increase due to increased product volume from commercial sales and product provided under our patient assistance programs, a \$6.8 million increase from cost of supply provided under our collaboration with Sobi, a \$4.3 million increase in royalty expense, and a \$1.1 million increase in expenses incurred related to excess or obsolete inventory.

In addition, prior to receiving FDA approval for EMPAVELI and SYFOVRE, the costs associated with the manufacturing of EMPAVELI and SYFOVRE inventory were expensed as incurred as research and development expense. This resulted in inventory being sold for the six months ended June 30, 2023 and 2022 for which a portion of the costs had been previously expensed prior to FDA approval. We expect this to continue to impact the cost of sales as the remaining pre-FDA approval inventory is sold to customers.

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the six months ended June 30, 2023 and 2022 (in thousands, except percentages):

	For the Six Months Ended June 30,		Change \$	Change %
	2023	2022		
Clinical trial costs	\$ 44,404	\$ 49,434	\$ (5,030)	(10 %)
Compensation and related personnel costs	97,600	76,895	20,705	27 %
Contract manufacturing	4,052	23,606	(19,554)	(83 %)
Sobi development milestone	—	(4,993)	4,993	(100 %)
Research/innovation costs	16,580	9,068	7,512	83 %
Other development costs	36,849	32,548	4,301	13 %
Pre-clinical study expenses	4,653	5,781	(1,128)	(20 %)
Device development expenses	1,546	267	1,279	479 %
Research and development expenses	205,684	192,606	13,078	7 %

Research and development expenses increased by \$13.1 million to \$205.7 million for the six months ended June 30, 2023 from \$192.6 million for the six months ended June 30, 2022, an increase of 7%. The increase was primarily attributable to an increase of \$20.7 million in personnel related costs due to having more employees in the six months ended June 30, 2023, an increase of \$7.5 million in research and innovation costs, an increase of \$4.3 million in other development costs, and an increase of \$1.3 million in device development expenses. In addition, there was no contra research and development expenses recorded under the Sobi collaboration agreement for the six months ended June 30, 2023 as compared to \$5.0 million for the six months ended June 30, 2022. The increases were partially offset by a decrease of \$5.0 million in clinical trial costs due to the completion of our Phase 3 DERBY and OAKS trials, a decrease of \$19.6 million in contract manufacturing expenses due primarily to the timing of drug supply and analytical activity, and a decrease of \$1.1 million in preclinical study expenses.

General and Administrative Expenses

General and administrative expenses increased by \$99.1 million to \$213.5 million for the six months ended June 30, 2023, from \$114.4 million for the six months ended June 30, 2022, an increase of 87%. The increase was primarily attributable to an increase in employee related costs of \$45.7 million, an increase in professional and consulting fees and general commercial preparation activities of \$48.6 million, an increase in travel related expenses of \$3.3 million, higher office costs of \$1.2 million, and an increase in director stock option compensation of \$0.4 million. The increase was partially offset by lower insurance expenses of \$0.1 million. The increase in employee related costs of \$45.7 million consisted of a \$37.8 million increase in salaries and benefits primarily due to the higher number of employees in the period, an increase of \$9.6 million related to stock compensation expense associated with the grant of stock options and restricted stock units to employees, offset by a decrease of \$1.7 million in recruiting expenses. The increase in other professional and consulting fees and general commercial preparation activities of \$48.6 million primarily related to higher commercialization related activity of \$44.2 million, and an increase in general professional fees of \$4.4 million.

Interest Income

Interest income was \$11.4 million for the six months ended June 30, 2023, an increase of \$9.9 million compared to \$1.5 million for the six months ended June 30, 2022. The increase in interest income was primarily attributable to increased money market interest rates during the six months ended June 30, 2023.

Interest Expense

Interest expense was \$14.9 million for the six months ended June 30, 2023, a decreased of \$2.1 million compared to \$17.0 million for the six months ended June 30, 2022. The decrease is primarily due to lower outstanding principal amount of our convertible notes.

Other (Expense)/Income, Net

Other expense was \$0.3 million for the six months ended June 30, 2023 and \$0.1 million for the six months ended June 30, 2022. Other expense increase was primarily due to foreign currency revaluation losses.

Income Tax Expense

Income tax expense was \$0.5 million for the six months ended June 30, 2023 decrease of \$1.2 million, compared to \$1.7 million for the six months ended June 30, 2022. The decrease primarily pertained to a decrease in U.S. taxable income, driven in part by lower research and development capitalization.

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 our convertible notes, a \$250.0 million up-front payment and a \$65.0 million development reimbursement payments 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 have exchanged \$425.4 million of aggregate principal amount of our convertible notes for shares of our common stock.

In May 2020, we completed a private offering of \$300.0 million aggregate principal amount of convertible notes, or the 2020 Convertible Notes and, together with the 2019 Convertible Notes, the Convertible Notes. We received net proceeds of approximately \$322.9 million, which included accrued interest from 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 the Convertible Notes held by them for an aggregate of 5,992,217 shares of our common stock. These exchange transactions closed in July 2021.

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.

In February 2023, we issued and sold 4,007,936 shares of our common stock and, in lieu of common stock to investor who so chose, pre-funded warrants to purchase 2,380,956 shares of our common stock in a follow-on offering, including 833,333 shares sold pursuant to the underwriters' exercise in full of their option to purchase additional shares of common stock. The price to the public of the shares of common stock was \$63.00 per share and the price to the public of the pre-funded warrants was \$62.9999 per pre-funded warrant. The pre-funded warrants have an exercise price equal to \$0.0001 per share and do not expire. The pre-funded warrants were accounted for as equity instruments. We received total net proceeds of \$384.4 million, after deducting underwriting discounts and commissions of \$18.8 million and offering cost of \$0.3 million.

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, 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 our common stock, as measured under the terms of the capped call transactions, exceeds \$63.14, the cap price of the capped call transactions, 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.

Refer to Note 8 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.

In addition, our cash deposits may exceed federally insured limits, and we are exposed to credit risk on deposits in the event of default by the financial institutions to the extent account balances exceed the amount insured by the Federal Deposit Insurance Corporation (FDIC). On March 10, 2023, SVB, where we maintained operating accounts with a cash balance representing approximately 20% of our total cash and cash equivalents, was closed by the California Department of Financial Protection and Innovation and the FDIC was appointed as receiver. On March 12, 2023, the U.S. Department of the Treasury, Federal Reserve Board, and FDIC released a joint statement announcing that the FDIC would complete its resolution of SVB in a manner that fully protected all depositors at SVB. On March 27, 2023, First Citizens Bank & Trust Company assumed all of SVB's deposits and loans. In light of the foregoing, we did not experience any loss of its cash balances that were held at SVB as a result of SVB's receivership and subsequent assumption.

Cash Flows

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

	<u>For the Six Months Ended June 30,</u>	
	<u>2023</u>	<u>2022</u>
Net cash used in operating activities	\$ (327,775)	\$ (218,584)
Net cash (used in) investing activities	(631)	(189,020)
Net cash provided by financing activities	392,666	371,969
Effect of exchange rate changes on cash, cash equivalents and restricted cash	9	(365)
Net increase/(decrease) in cash, cash equivalents and restricted cash	<u>\$ 64,269</u>	<u>\$ (36,000)</u>

Net Cash Used in Operating Activities

Net cash used in operating activities was \$327.8 million for the six months ended June 30, 2023 and consisted primarily of a net loss of \$299.8 million adjusted for \$72.2 million of non-cash items, including share-based compensation expense of \$58.1 million, depreciation expense of \$0.8 million, accretion of discount to the development liability of \$13.1 million. Further, it includes a net decrease in operating assets of \$93.3 million, a decrease in accounts payable of \$9.8 million and an increase in accrued expenses of \$3.1 million.

Net cash used in operating activities was \$218.6 million for the six months ended June 30, 2022 and consisted primarily of a net loss of \$294.9 million adjusted for \$59.2 million of non-cash items, including share-based compensation expense of \$43.3 million, depreciation expense of \$0.8 million, accretion of discounts for the Convertible Notes of \$0.2 million, accretion of discount to the development liability of \$13.3 million, and other liabilities of \$1.6 million. Further, it includes a net increase in current operating assets of \$16.1 million, an increase in other assets of \$15.8 million, an increase in accounts payable of \$2.6 million and a decrease in accrued expenses of \$17.3 million.

Net Cash Used in Investing Activities

Net cash used in investing activities during the six months ended June 30, 2023 was \$0.6 million due primarily to purchases of fixed assets.

Net cash used in investing activities during the six months ended June 30, 2022 was \$189.0 million due primarily to the purchase and maturity of marketable securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$392.7 million during the six months ended June 30, 2023 and consisted primarily of proceeds from the follow-on common stock and pre-funded warrant offering in March 2023 of \$384.4 million, \$40.1 million proceeds upon the exercise of stock options and \$3.8 million proceeds from the issuance of our common stock under the employee stock purchase plan partially offset by payments of \$24.5 million for the development liability as well as the payments of employee tax withholding related to equity-based compensation of \$11.0 million.

Net cash provided by financing activities was \$372.0 million during the six months ended June 30, 2022 and consisted primarily of proceeds from the follow-on common stock offering in March 2022 of \$380.1 million, \$8.8 million proceeds upon the exercise of stock options and \$2.5 million proceeds from the issuance of our common stock under the employee stock purchase plan partially offset by payments of \$16.5 million for the development liability as well as \$3.0 million for the payments 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 for PNH and commercialization activities related to SYFOVRE 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.

We believe that our cash and cash equivalents as of June 30, 2023, along with cash anticipated to be generated from sales of EMPAVELI and SYFOVRE, as well as the remaining committed development reimbursement payment from Sobi, will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2025. 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 substantial resources to the building of a commercial infrastructure for SYFOVRE 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 and SYFOVRE and development of 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 and SYFOVRE in the United States;
- the cost of and our ability to submit applications for regulatory approval outside of the United States and to build a commercial infrastructure for SYFOVRE for GA in the United States and worldwide;
- 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 SYFOVRE 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 systemic pegcetacoplan, SYFOVRE and our other 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 any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of any 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 public health crises, including pandemics and epidemics, 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 and SYFOVRE 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 2022 Annual Report on Form 10-K. See Note 15 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 June 30, 2023, we had cash and cash equivalents of \$616.3 million, consisting primarily of money market funds and U.S. Government obligations. 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 June 30, 2023.

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 June 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control 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 set forth below and those discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2022, which could materially affect our business, financial condition or future results. The risk factors disclosure below and in our Annual Report on Form 10-K for the year ended December 31, 2022 is qualified by the information that is described in this Quarterly Report on Form 10-Q. The risks described below and in our Annual Report on Form 10-K for the year ended December 31, 2022 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.

We or others may later discover that EMPAVELI or SYFOVRE is less effective than previously believed or causes safety issues that were not previously identified, which could compromise our ability, or that of our collaborators, to market the product.

Clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of our collaborators, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify safety issues that may be observed once the product has been commercialized. If safety problems occur or are identified after EMPAVELI or SYFOVRE or one of our products, if any, reaches the market, the FDA or comparable non-U.S. regulatory authorities may require that we amend the labeling of our product, recall our product, or even withdraw approval for our product.

In July 2023, we disclosed that we had confirmed seven events of retinal vasculitis and were evaluating one reported event of retinal vasculitis following SYFOVRE treatment. We are working with the retinal community to investigate potential contributing factors. We will continue to submit all adverse events reported to us to the FDA consistent with reporting guidelines for drug manufacturers. We cannot provide any assurances that the FDA and the retinal community will continue to believe that the expected benefits of SYFOVRE treatment outweigh its potential risks to patients following these reported events or that our applications for marketing approval of SYFOVRE in other jurisdictions will not be adversely impacted. A change in the perception of the benefit/risk profile of SYFOVRE may reduce market acceptance of the product and our product revenues may be adversely affected.

If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes safety issues that were not previously identified, such as the reported events of retinal vasculitis following SYFOVRE treatment, any of the following events could occur:

- the target patient population may be less willing to try, and physicians may be less willing to prescribe, the product;
- regulatory authorities may withdraw their approval of the product or seize the product;
- we, or our collaborators, may be required to recall the product, change the way the product is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we, or our collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or our collaborators, could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could harm our business and operations, affect sales of our products and negatively impact our stock price.

Item 5. Other Information.

The following table describes, for the quarterly period covered by this report, each trading arrangement for the sale or purchase of our securities adopted or terminated by our directors and officers that is either (1) a contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c), or a Rule 10b5-1 trading arrangement, or (2) a “non-Rule 10b5-1 trading arrangement” (as defined in Item 408(c) of Regulation S-K):

Name (Title)	Action Taken (Date of Action)	Type of Trading Arrangement	Nature of Trading Arrangement	Duration of Trading Arrangement	Aggregate Number of Securities
Lucas Scheibler Chief Innovation Officer	Adoption 5/15/2023	Rule 10b5-1 trading arrangement	Sale	Until 1/31/2024, or such earlier date upon which all transactions are completed or expire without execution	Up to 125,849 shares
David Watson General Counsel	Adoption 5/18/2023	Rule 10b5-1 trading arrangement	Sale	Until 12/29/2023, or such earlier date upon which all transactions are completed or expire without execution	Up to 26,555 shares
Cedric Francois President and Chief Executive	Adoption 5/25/2023	Rule 10b5-1 trading arrangement	Sale	Until 12/04/2023, or such earlier date upon which all transactions are completed or expire without execution	Up to 300,000 shares
Adam Townsend Chief Commercial Officer	Adoption 5/25/2023	Rule 10b5-1 trading arrangement	Sale	Until 12/29/2023, or such earlier date upon which all transactions are completed or expire without execution	Up to 110,000 shares
Stephanie O Brien Director	Adoption 5/26/2023	Rule 10b5-1 trading arrangement	Sale	Until 5/15/2024, or such earlier date upon which all transactions are completed or expire without execution	Up to 22,500 shares
Jeffrey Eisele Chief Development Officer	Adoption 5/30/2023	Rule 10b5-1 trading arrangement	Sale	Until 2/29/2024, or such earlier date upon which all transactions are completed or expire without execution	Up to 63,683 shares
A Sinclair Dunlop Director	Termination 5/31/2023	Rule 10b5-1 trading arrangement	Sale	(1)	(1)
A Sinclair Dunlop (2) Director	Adoption 6/1/2023	Rule 10b5-1 trading arrangement	Sale	Until 2/29/2024, or such earlier date upon which all transactions are completed or expire without execution	Up to 240,681 shares
Nur Nicholson Chief Technical Operations	Adoption 6/8/2023	Rule 10b5-1 trading arrangement	Sale	Until 6/07/2024, or such earlier date upon which all transactions are completed or expire without execution	Up to 67,000 shares
Pascal Deschatelets Chief Scientific Officer	Adoption 6/9/2023	Rule 10b5-1 trading arrangement	Sale	Until 3/28/2024, or such earlier date upon which all transactions are completed or expire without execution	Up to 138,214 shares
Karen L Lewis Chief People Officer	Adoption 6/26/2023	Rule 10b5-1 trading arrangement	Sale	Until 8/30/2024, or such earlier date upon which all transactions are completed or expire without execution	Up to 92,182 shares

- (1) This trading plan related to 6,000 shares of our common stock and had a scheduled expiration date of 7/31/2024.
- (2) This trading plan was established by Epidarex Capital I, LP, of which Mr. Dunlop is the co-founder and managing partner. Mr. Dunlop may be deemed to have voting and investment power over the shares subject to the trading plan.

Item 6. Exhibits.

Exhibit Number	Description
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: July 31, 2023

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

Date: July 31, 2023

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: July 31, 2023

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: July 31, 2023

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 June 30, 2023 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: July 31, 2023

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 June 30, 2023 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: July 31, 2023

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.
