

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

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): July 31, 2023

Apellis Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38276
(Commission
File Number)

27-1537290
(IRS Employer
Identification No.)

100 Fifth Avenue
Waltham, MA
(Address of Principal Executive Offices)

02451
(Zip Code)

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

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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	APLS	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02 Results of Operations and Financial Condition

On July 31, 2023, Apellis Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2023 and other business highlights. The full text of the press release issued by the Company in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Released dated July 31, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

Apellis Pharmaceuticals, Inc.

Date: July 31, 2023

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



Apellis Pharmaceuticals Reports Second Quarter 2023 Financial Results

- Generated total U.S. net product revenues of \$89.6 million, including \$67.3 million for SYFOVRE® (pegcetacoplan injection) and \$22.3 million for EMPAVELI® (pegcetacoplan)
- SYFOVRE reduced nonsubfoveal GA lesion growth by up to 45% between Months 24-30 compared to projected sham in the GALE long-term extension study
- Investigation on recently reported rare safety events with real-world use of SYFOVRE has found no indication that drug product or manufacturing issues contributed to events
- Cash and cash equivalents of \$616.3 million as of June 30, 2023

WALTHAM, Mass., July 31, 2023 (GLOBE NEWSWIRE) – Apellis Pharmaceuticals, Inc. (Nasdaq: APLS), a global biopharmaceutical company and leader in complement, today announced its second quarter 2023 financial results and business highlights.

“We made important progress in the second quarter, highlighted by strong commercial execution of the SYFOVRE launch, continued momentum in PNH, and the advancement of APL-3007 into a Phase 1 study. With more than 68,000 SYFOVRE vials distributed through July, we continue to work with the retina community to bring the first and only approved treatment for GA to patients,” said Cedric Francois, M.D., Ph.D., co-founder and chief executive officer of Apellis. “Following the rare events of retinal vasculitis with SYFOVRE in the real world, we began conducting a comprehensive investigation into the potential causes of these events and have found no indication of drug product or manufacturing issues. Patient safety is our top priority, and we are continuing our ongoing review with external experts.”

“We also continue to strengthen our understanding of the long-term safety and efficacy of SYFOVRE. Results from our GALE extension study showed that SYFOVRE continues to demonstrate increasing effects over time, with a reduction in nonsubfoveal GA lesion growth of up to 45% between months 24 and 30. Additionally, the safety profile continued to be consistent with previously reported clinical data. We are committed to making a difference for people living with GA, PNH, and other serious complement-driven diseases, and I’d like to thank our team for their incredible dedication and for always putting patients first.”

Second Quarter 2023 Business Highlights and Upcoming Milestones

Ophthalmology Highlights

- SYFOVRE for the treatment of GA secondary to AMD:
 - Apellis reported \$67.3 million in SYFOVRE U.S. net product revenue for the second quarter of 2023.
 - More than 31,000 commercial vials and nearly 11,000 samples of SYFOVRE were delivered to physician practices in the second quarter; total vials delivered since launch through July 29, 2023 is more than 68,000.
 - In an oral presentation at the American Society of Retina Specialists Annual Scientific Meeting, [results](#) from the GALE long-term extension study demonstrated that SYFOVRE reduced nonsubfoveal GA lesion growth by up to 45% between Months 24-30 compared to projected sham arm; the safety profile continued to be consistent with previously reported Phase 3 data.
 - The company is conducting a comprehensive investigation into possible causes of the reported cases of retinal vasculitis. To date, there is no indication that drug product or manufacturing issues contributed to the events. The company reports all safety events to the FDA consistent with reporting guidelines for manufacturers.
 - Marketing applications for intravitreal pegcetacoplan for the treatment of GA secondary to AMD are under review in the EU, Canada, Australia, the United Kingdom and Switzerland. A decision by the European Medicines Agency is expected in early 2024; decisions by the local regulatory authorities in the other countries are expected in the first half of 2024.

Paroxysmal Nocturnal Hemoglobinuria (PNH) Highlights

- *EMPAVELI for the treatment of PNH:*
 - Apellis reported \$22.3 million in EMPAVELI U.S. net product revenue for the second quarter 2023.
 - More than 230 patients with PNH were on commercial treatment with EMPAVELI as of June 30, 2023.
 - In March 2023, the company was notified by the FDA that the FDA would miss the Prescription Drug User Fee Act (PDUFA) target action date of March 15, 2023 for Apellis' sNDA application for the EMPAVELI Injector. The company continues to engage with the FDA as the review is ongoing. EMPAVELI Injector is a compact, on-body drug delivery system that features several advancements to streamline self-administration of EMPAVELI.

Rare Disease R&D Highlights

- *Amyotrophic lateral sclerosis (ALS):* In May 2023, Apellis and Sobi discontinued development of systemic pegcetacoplan for ALS following top-line results from the Phase 2 MERIDIAN study.
 - The study did not meet its primary endpoint or key secondary efficacy endpoints at Week 52. Systemic pegcetacoplan was well tolerated in the study, and the data were consistent with the established safety profile.
- *Immune complex membranoproliferative glomerulonephritis (IC-MPGN) and C3 glomerulopathy (C3G):* Apellis continues to enroll patients in the Phase 3 VALIANT study of systemic pegcetacoplan for IC-MPGN and C3G. Top-line data from this study is expected in 2024.
- *Cold agglutinin disease (CAD):* Sobi, Apellis' global co-development partner for systemic pegcetacoplan, continues to enroll patients in the Phase 3 CASCADE study of systemic pegcetacoplan for CAD.
- *Hematopoietic stem cell transplantation-associated thrombotic microangiopathy (HSCT-TMA):* Sobi continues to enroll patients in its Phase 2 study evaluating the efficacy and safety of systemic pegcetacoplan in patients with HSCT-TMA. Sobi expects data from this study in 2024.
- *C3 inhibition + siRNA:* In June 2023, Apellis enrolled its first patient in Phase 1 clinical trial with APL-3007.

Neurology R&D Highlights

- *APL-1030:* Apellis continues to advance pre-clinical studies of APL-1030, a first-in-class, brain-active C3 inhibitor for neurological diseases.

Second Quarter 2023 Financial Results

Cash. As of June 30, 2023, Apellis had \$616.3 million in cash and cash equivalents, compared to \$551.8 million in cash and cash equivalents as of December 31, 2022. Apellis anticipates its cash balance, combined with cash anticipated to be generated from sales of EMPAVELI and SYFOVRE and Sobi reimbursements, to fund operations into the first quarter of 2025.

Total Revenue.

- Total revenue was \$95.0 million for the second quarter of 2023, which consisted of \$22.3 million of U.S. net product revenue of EMPAVELI, \$67.3 million of U.S. net product revenue of SYFOVRE, and additional licensing and other revenue under the Sobi collaboration.
 - Total revenue was \$16.3 million for the second quarter of 2022, which consisted of \$15.7 million in net product revenue from sales of EMPAVELI and \$0.6 million in revenue associated with the Sobi collaboration.

Cost of Sales.

- Cost of sales were \$8.4 million for the second quarter 2023, compared to \$0.1 million for same period in 2022. Cost of sales consists primarily of costs associated with the manufacturing of SYFOVRE and EMPAVELI, royalties owed to our licensor for such sales, costs associated with Sobi revenue, and certain period costs.
 - Prior to receiving FDA approval for EMPAVELI in May 2021 and SYFOVRE in February 2023, costs associated with the manufacturing of EMPAVELI and SYFOVRE inventory were expensed as research and development (R&D) expense. This resulted in inventory being sold during the periods ended June 30, 2023, and June 30, 2022, for which a portion of the costs had been previously expensed prior to FDA approval.

R&D Expenses.

- R&D expenses were \$95.7 million for the second quarter of 2023, compared to \$101.7 million for the same period in 2022.
 - The decrease in R&D expenses for the second quarter 2023 was primarily attributable to a decrease in contract manufacturing expenses of \$13.1 million and a decrease in clinical trial and preclinical trial expenses. The decreases were partially offset by an \$8.4 million increase in personnel related costs, an increase in research and innovation costs, and an increase in device developments costs.

General and Administrative (G&A) Expenses.

- G&A expenses were \$111.4 million for the second quarter of 2023, compared to \$63.2 million for the same period in 2022.
 - The increase in G&A expenses for the second quarter of 2023 was primarily attributable to an increase in employee related costs of \$22.1 million, an increase in professional and consulting fees and general commercial preparation activities of \$24.5 million, and an increase in travel related expenses, higher office costs, and an increase in director stock option compensation.

Net Loss. Apellis reported a net loss of \$122.0 million for the second quarter 2023, compared to a net loss of \$156.0 million for the same period in 2022.

Conference Call and Webcast

Apellis will host a conference call and webcast to discuss its second quarter 2023 financial results and business highlights today, July 31, 2023, at 8:30 a.m. ET. To access the live call by phone, please pre-register for the call [here](#). A live audio webcast of the event and accompanying slides may also be accessed through the “Events and Presentations” page of the “Investors and Media” section of the company’s [website](#). A replay of the webcast will be available for 30 days following the event.

About SYFOVRE® (pegcetacoplan injection)

SYFOVRE® (pegcetacoplan injection) is the first and only approved therapy for geographic atrophy (GA). By targeting C3, SYFOVRE is designed to provide comprehensive control of the complement cascade, part of the body’s immune system. SYFOVRE is approved in the United States for the treatment of GA secondary to age-related macular degeneration.

About EMPAVELI®/Aspaveli® (pegcetacoplan)

EMPAVELI®/Aspaveli® (pegcetacoplan) is a targeted C3 therapy designed to regulate excessive activation of the complement cascade, part of the body’s immune system, which can lead to the onset and progression of many serious diseases. It is approved for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) in the United States, European Union, and other countries globally. The therapy is also under investigation for several other rare diseases across hematology and nephrology.

U.S. Important Safety Information for SYFOVRE® (pegcetacoplan injection)

CONTRAINDICATIONS

- SYFOVRE is contraindicated in patients with ocular or periocular infections, and in patients with active intraocular inflammation.

WARNINGS AND PRECAUTIONS

- Endophthalmitis and Retinal Detachments
 - Intravitreal injections, including those with SYFOVRE, may be associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering SYFOVRE to minimize the risk of endophthalmitis. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately.
- Neovascular AMD
 - In clinical trials, use of SYFOVRE was associated with increased rates of neovascular (wet) AMD or choroidal neovascularization (12% when administered monthly, 7% when administered every other month and 3% in the control group) by Month 24. Patients receiving SYFOVRE should be monitored for signs of neovascular AMD. In case anti-Vascular Endothelial Growth Factor (anti-VEGF) is required, it should be given separately from SYFOVRE administration.
- Intraocular Inflammation
 - In clinical trials, use of SYFOVRE was associated with episodes of intraocular inflammation including: vitritis, vitreal cells, iridocyclitis, uveitis, anterior chamber cells, iritis, and anterior chamber flare. After inflammation resolves, patients may resume treatment with SYFOVRE.
- Increased Intraocular Pressure
 - Acute increase in IOP may occur within minutes of any intravitreal injection, including with SYFOVRE. Perfusion of the optic nerve head should be monitored following the injection and managed as needed.

ADVERSE REACTIONS

- Most common adverse reactions (incidence $\geq 5\%$) are ocular discomfort, neovascular age-related macular degeneration, vitreous floaters, conjunctival hemorrhage.

Please see accompanying full [Prescribing Information](#) for more information.

U.S. Important Safety Information for EMPAVELI

BOXED WARNING: SERIOUS INFECTIONS CAUSED BY ENCAPSULATED BACTERIA

- **Meningococcal infections may occur in patients treated with EMPAVELI and may become rapidly life-threatening or fatal if not recognized and treated early. Use of EMPAVELI may predispose individuals to serious infections, especially those caused by encapsulated bacteria, such as *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B.**
- **Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria.**
- **Vaccinate patients at least 2 weeks prior to administering the first dose of EMPAVELI unless the risks of delaying therapy with EMPAVELI outweigh the risk of developing a serious infection.**
- **Vaccination reduces, but does not eliminate, the risk of serious infections. Monitor patients for early signs of serious infections and evaluate immediately if infection is suspected.**
- **EMPAVELI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the EMPAVELI REMS, prescribers must enroll in the program.**

CONTRAINDICATIONS

- Hypersensitivity to pegcetacoplan or to any of the excipients
- Not currently vaccinated against certain encapsulated bacteria, unless the risks of delaying EMPAVELI treatment outweigh the risks of developing a bacterial infection with an encapsulated organism
- Unresolved serious infection caused by encapsulated bacteria including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae*

WARNINGS AND PRECAUTIONS

Serious Infections Caused by Encapsulated Bacteria

The use of EMPAVELI may predispose individuals to serious, life-threatening, or fatal infections caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B (Hib). To reduce the risk of infection, all patients must be vaccinated against these bacteria according to the most current ACIP recommendations for patients with altered immunocompetence associated with complement deficiencies. Revaccinate patients in accordance with ACIP recommendations considering the duration of therapy with EMPAVELI.

For patients without known history of vaccination, administer required vaccines at least 2 weeks prior to receiving the first dose of EMPAVELI. If immediate therapy with EMPAVELI is indicated, administer required vaccine as soon as possible and provide patients with 2 weeks of antibacterial drug prophylaxis.

Closely monitor patients for early signs and symptoms of serious infection and evaluate patients immediately if an infection is suspected. Promptly treat known infections. Serious infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider discontinuation of EMPAVELI in patients who are undergoing treatment for serious infections.

EMPAVELI REMS

Because of the risk of serious infections, EMPAVELI is available only through a restricted program under a REMS. Under the EMPAVELI REMS, prescribers must enroll in the program and must counsel patients about the risk of serious infection, provide the patients with the REMS educational materials, and ensure patients are vaccinated against encapsulated bacteria. Enrollment and additional information are available by telephone: 1-888-343-7073 or at www.empavelirems.com.

Infusion-Related Reactions

Systemic hypersensitivity reactions (e.g., facial swelling, rash, urticaria) have occurred in patients treated with EMPAVELI. One patient (less than 1% in clinical studies) experienced a serious allergic reaction which resolved after treatment with antihistamines. If a severe hypersensitivity reaction (including anaphylaxis) occurs, discontinue EMPAVELI infusion immediately, institute appropriate treatment, per standard of care, and monitor until signs and symptoms are resolved.

Monitoring PNH Manifestations after Discontinuation of EMPAVELI

After discontinuing treatment with EMPAVELI, closely monitor for signs and symptoms of hemolysis, identified by elevated LDH levels along with sudden decrease in PNH clone size or hemoglobin, or reappearance of symptoms such as fatigue, hemoglobinuria, abdominal pain, dyspnea, major adverse vascular events (including thrombosis), dysphagia, or erectile dysfunction. Monitor any patient who discontinues EMPAVELI for at least 8 weeks to detect hemolysis and other reactions. If hemolysis, including elevated LDH, occurs after discontinuation of EMPAVELI, consider restarting treatment with EMPAVELI.

Interference with Laboratory Tests

There may be interference between silica reagents in coagulation panels and EMPAVELI that results in artificially prolonged activated partial thromboplastin time (aPTT); therefore, avoid the use of silica reagents in coagulation panels.

ADVERSE REACTIONS

Most common adverse reactions in patients with PNH (incidence $\geq 10\%$) were injection-site reactions, infections, diarrhea, abdominal pain, respiratory tract infection, pain in extremity, hypokalemia, fatigue, viral infection, cough, arthralgia, dizziness, headache, and rash.

USE IN SPECIFIC POPULATIONS

Females of Reproductive Potential

EMPAVELI may cause embryo-fetal harm when administered to pregnant women. Pregnancy testing is recommended for females of reproductive potential prior to treatment with EMPAVELI. Advise female patients of reproductive potential to use effective contraception during treatment with EMPAVELI and for 40 days after the last dose.

Please see full Prescribing Information, including **Boxed WARNING regarding serious infections caused by encapsulated bacteria, and Medication Guide.**

About Apellis

Apellis Pharmaceuticals, Inc. is a global biopharmaceutical company that combines courageous science and compassion to develop life-changing therapies for some of the most challenging diseases patients face. We ushered in the first new class of complement medicine in 15 years and now have two approved medicines targeting C3. These include the first and only therapy for geographic atrophy, a leading cause of blindness around the world. With nearly a dozen clinical and pre-clinical programs underway, we believe we have only begun to unlock the potential of targeting C3 across many serious diseases. For more information, please visit <http://apellis.com> or follow us on [Twitter](#) and [LinkedIn](#).

Apellis Forward-Looking Statement

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute “forward-looking statements” within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements regarding the safety profile of SYFOVRE. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including whether the benefit/risk profile of SYFOVRE following these reported safety events will impact our commercialization efforts; whether SYFOVRE will receive approval from foreign regulatory agencies for GA when expected or at all, including the impact on the likelihood and timing of such approvals of the reported events of retinal vasculitis; whether the company’s clinical trials will be fully enrolled and completed when anticipated; whether preliminary or interim results from a clinical trial will be predictive of the final results of the trial; whether results obtained in preclinical studies and clinical trials will be indicative of results that will be generated in future clinical trials; whether pegcetacoplan will successfully advance through the clinical trial process on a timely basis, or at all; whether the results of the company’s clinical trials will warrant regulatory submissions and whether systemic pegcetacoplan will receive approval from the FDA or equivalent foreign regulatory agencies for CAD, C3G, IC-MPGN, HSCT-TMA, ALS or any other indication when expected or at all; the period for which the Apellis believes that its cash resources will be sufficient to fund its operations; and other factors discussed in the “Risk Factors” section of Apellis’ Annual Report on Form 10-K with the Securities and Exchange Commission on February 21, 2023 and the risks described in other filings that Apellis may make with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Apellis specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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

	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
	(Unaudited)	
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	<u>892,686</u>	<u>719,523</u>
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	<u>174,837</u>	<u>167,610</u>
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	<u>570,175</u>	<u>590,345</u>
Commitments and contingencies (Note 14)	—	—
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000 shares authorized and zero shares issued and outstanding at 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	<u>345,403</u>	<u>169,872</u>
Total liabilities and stockholders' equity	<u>\$ 915,578</u>	<u>\$ 760,217</u>

APELLIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(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>
	(Unaudited)		(Unaudited)	
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:	94,969	16,322	139,814	30,703
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:	215,410	164,946	435,338	308,325
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	\$ (122,037)	\$ (155,977)	\$ (299,815)	\$ (294,912)
Other comprehensive (loss)/gain:				
Unrealized (loss)/gain on marketable securities	—	(766)	—	(818)
Foreign currency gain/(loss)	(21)	(369)	79	(286)
Total other comprehensive income/(loss)	(21)	(1,135)	79	(1,104)
Comprehensive loss, net of tax	\$ (122,058)	\$ (157,112)	\$ (299,736)	\$ (296,016)
Net loss per common share, basic and diluted	\$ (1.02)	\$ (1.46)	\$ (2.57)	\$ (2.88)
Weighted-average number of common shares used in net loss per common share, basic and diluted	119,316	106,630	116,594	102,349