

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): August 13, 2026

Invivyd, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40703
(Commission
File Number)

85-1403134
(IRS Employer
Identification No.)

205 Church Street
New Haven, CT
(Address of Principal Executive Offices)

06510
(Zip Code)

Registrant's telephone number, including area code: (781) 819-0080

209 Church Street, New Haven, CT 06510
(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:

- ☐ 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, par value \$0.0001 per share	IVVD	The Nasdaq Stock Market LLC

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 August 13, 2026, Invivyd, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2026, and recent business highlights. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 2.02.

The information furnished pursuant to this Item 2.02, including Exhibit 99.1, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any of the Company’s filings with the Securities and Exchange Commission under the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 13, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

INVIVYD, INC.

Date: August 13, 2026

By: /s/ Jill Andersen

Jill Andersen

Chief Legal Officer and Corporate Secretary

Invivyd Reports Second Quarter 2026 Financial Results and Recent Business Highlights

- *Achieved Q2 2026 PEMGARDA® (pemivibart) net product revenue of \$14.3 million, representing 21% growth versus Q2 2025 net product revenue of \$11.8 million*
- *Completed rapid enrollment in VYD2311 DECLARATION clinical trial expansion cohort and LIBERTY clinical trial, driven by strong subject demand*
- *DECLARATION pivotal clinical trial enrollment is complete; the ongoing study is approaching its planned analysis, and in lieu of a Q2 2026 quarterly earnings call, Invivyd plans to hold an investor call post study completion*
- *LIBERTY study fully dosed with top-line data anticipated in late Q3 2026*
- *Strong balance sheet with Q2 2026 ending cash and cash equivalents of \$160.1 million anticipated to provide runway through DECLARATION pivotal data readout and support potential commercial launch readiness for VYD2311*

NEW HAVEN, Conn., August 13, 2026 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced financial results for the second quarter ended June 30, 2026, and recent business highlights.

"With our VYD2311 DECLARATION and LIBERTY clinical trials planned to wrap up in the coming weeks, we are looking forward to the next steps for vulnerable Americans," said Marc Elia, Chairman of the Board of Invivyd. "The public health need for antibody-based protection with attractive safety is enormous, and we are confident that many public health leaders and policy makers in the United States understand the importance of having non-vaccine options available for the American public health."

"We are pleased with continued growth of PEMGARDA, especially in the face of understandably diminished COVID vaccine utilization," commented Bill Duke, Chief Financial Officer of Invivyd. "We are pleased with our strong cash position as we approach planned top-line data for our VYD2311 pivotal program later this quarter. We have continued to diligently manage expenses, albeit during a period of critical heavy clinical investment in our pivotal VYD2311 program, which we expect to complete shortly as we move toward potential launch of VYD2311, if approved."

Second Quarter 2026 and Recent Company Highlights

PEMGARDA® Commercial Performance & Regulatory Update

- PEMGARDA net product revenue was \$14.3 million for the quarter ended June 30, 2026, compared to \$11.8 million in for the quarter ended June 30, 2025. Growth of 21% was driven by increased patient demand.
- In July 2026, Invivyd announced receipt of twelve months' advanced notice of emergency use authorization (EUA) termination for PEMGARDA and that the company is in dialogue with the U.S. Food and Drug Administration (FDA) about appropriate next steps.

Research & Development (R&D) Highlights

COVID-19

- Invivyd continued to advance its REVOLUTION program, which is Invivyd's development program for VYD2311 that is designed to elaborate the profile of monoclonal antibody-mediated prophylaxis from COVID-19 and the potential medical benefits to vulnerable Americans:
 - **DECLARATION:** Following trial initiation in late 2025, the DECLARATION pivotal clinical trial recruitment progressed rapidly with full initial enrollment achieved in March 2026. In April 2026, Invivyd announced it had conducted a prospectively designed, conservative, algorithmic sample size re-estimation pooled, blinded analysis for the DECLARATION clinical trial aimed at supporting adequate COVID-19 clinical events and associated statistical power given the variability of COVID-19 attack rates, and, in June 2026, Invivyd announced completion of enrollment in the upsized DECLARATION clinical trial. DECLARATION is designed to support potential Biologics License Application (BLA) submission, with top-line data planned later in Q3 2026.
 - **LIBERTY:** In June 2026, Invivyd announced first participants dosed and completion of enrollment in LIBERTY, a Phase 3 clinical trial to evaluate the safety and tolerability of VYD2311 antibody versus mRNA COVID vaccine and to characterize the safety and immunology of antibody and mRNA vaccine co-administration. The LIBERTY study is now fully dosed, with top-line data anticipated in late Q3 2026.
 - **DRUMMER:** Invivyd agreed with the FDA on an initial pediatric study plan to support potential BLA submission for VYD2311 in children aged 0-11 years; the DRUMMER pediatric clinical trial will be actioned only if the pivotal DECLARATION clinical trial is successful.
 - **Long COVID:** In January 2026, Invivyd and the SPEAR (Spike Protein Elimination and Recovery) Study Group announced the plan to initiate a Phase 2 clinical trial evaluating VYD2311 in individuals with Long COVID or COVID vaccine injury. The Phase 2 clinical trial is expected to be initiated mid-2026.

Measles

- In April 2026, Invivyd announced advancement of a measles monoclonal antibody candidate, VMS063. VMS063 is a novel, highly potent, broadly in vitro neutralizing, high resistance barrier, half-life-extended, potentially first- and best-in-class monoclonal antibody candidate for the treatment and prevention of measles. Invivyd has begun Investigational New Drug (IND)-enablement and regulatory outreach to advance VMS063 toward IND readiness in 2H 2026.

Respiratory Syncytial Virus (RSV)

- Invivyd expects to advance VBY329, a novel, potential best-in-class monoclonal antibody candidate being developed to prevent RSV among neonates, infants, and children, for development in pediatric RSV prophylaxis, a blockbuster pharmaceutical market in 2024,
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expected to grow to \$3-\$4 billion in annual revenues globally by 2030. Invivyd expects to advance VBY329 toward IND readiness in 2H 2026.

Corporate Updates

- In April 2026, Marc Elia spoke at the POLITICO Health Care Summit. During the session, Mr. Elia framed the evolving landscape of viral disease prevention, including the role of monoclonal antibodies in keeping Americans healthy moving forward.
- In April 2026, Invivyd launched “Antibodies for Any Body” in partnership with world ski champion Lindsey Vonn to inspire actions that support immune health.

Publications & Other R&D Updates

- In May 2026, Invivyd published a preprint “Safety first: should the high tolerability of intramuscular anti-spike COVID-19 monoclonal antibody change our expectations of vaccine safety?” [Linked here](#). The analysis supports the strong early tolerability profile of intramuscular-administered adintrevimab, a low-dose investigational monoclonal antibody for the prevention of COVID-19 that is the parent antibody to pemivibart and VYD2311.
- In May 2026, Invivyd reported positive, continued, in vitro neutralization data for PEMGARDA (pemivibart) and for VYD2311, the company’s vaccine alternative monoclonal antibody candidate for the prevention of COVID-19, against SARS-CoV-2 variant BA.3.2.2 (“Cicada”). Positive in vitro neutralization data for pemivibart against SARS-CoV-2 virus circulating in the U.S. over the past four years affirm Invivyd’s unique technology and reflect consistently stable target epitopes.

Second Quarter 2026 Financial Results

- **Revenue:** Reported Q2 2026 PEMGARDA net product revenue of \$14.3 million, compared to \$11.8 million in Q2 2025, representing a 21% increase.
 - **Cash Position:** Cash and cash equivalents were \$160.1 million as of June 30, 2026. Cash and cash equivalents are anticipated to provide runway through DECLARATION pivotal data readout and support potential commercial launch readiness for VYD2311.
 - **R&D Expenses:** R&D expenses were \$29.4 million for the quarter ended June 30, 2026, compared to \$9.6 million for the comparable period in 2025. This increase is primarily attributable to higher contract research costs associated with the DECLARATION and LIBERTY clinical trials for VYD2311.
 - **Selling, General & Administrative (SG&A) Expenses:** SG&A expenses were \$29.5 million for the quarter ended June 30, 2026, compared to \$16.6 million for the comparable period in 2025. This increase is primarily attributable to an increase in personnel, communications and commercial-related costs.
 - **Net Loss and Net Loss per Share:** Net loss was \$44.4 million for the quarter ended June 30, 2026, compared to \$14.7 million for the comparable period in 2025. Basic and diluted net
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loss per share was \$0.14 for the quarter ended June 30, 2026, compared to \$0.12 for the comparable period in 2025.

About PEMGARDA

PEMGARDA® (pemivibart) is a half-life extended investigational monoclonal antibody (mAb). PEMGARDA was engineered from adintrevimab, Invivyd's investigational mAb that has a robust safety data package and provided evidence of clinical efficacy in global Phase 2/3 clinical trials for the prevention and treatment of COVID-19. PEMGARDA has demonstrated in vitro neutralizing activity against major SARS-CoV-2 variants, including JN.1, KP.3.1.1, XEC, LP.8.1 and XFG. PEMGARDA targets the SARS-CoV-2 spike protein receptor binding domain (RBD), thereby inhibiting virus attachment to the human ACE2 receptor on host cells.

PEMGARDA (pemivibart) injection (4500 mg), for intravenous use is an investigational mAb that has not been approved, but has been authorized for emergency use by the U.S. FDA under an EUA for the pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. Recipients should not be currently infected with or have had a known recent exposure to an individual infected with SARS-CoV-2.

PEMGARDA is not authorized for use for the treatment of COVID-19, Long COVID, or COVID-19 Post-Vaccination Syndrome, or for post-exposure prophylaxis of COVID-19. Pre-exposure prophylaxis with PEMGARDA is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate-to-severe immune compromise who may derive benefit from COVID-19 vaccinations, should receive COVID-19 vaccination. In individuals who have recently received a COVID-19 vaccine, PEMGARDA should be administered at least 2 weeks after vaccination.

Anaphylaxis has been observed with PEMGARDA and the PEMGARDA Fact Sheet for Healthcare Providers includes a boxed warning for anaphylaxis. The most common adverse reactions included systemic infusion-related reactions and hypersensitivity reactions, local infusion site reactions, and infusion site infiltration or extravasation. For additional information, please see the PEMGARDA full product Fact Sheet for Healthcare Providers, including important safety information and boxed warning.

To support the EUA for PEMGARDA, an immunobridging approach was used to determine if PEMGARDA may be effective for pre-exposure prophylaxis of COVID-19. Immunobridging is based on the serum virus neutralizing titer-efficacy relationships identified with other neutralizing human mAbs against SARS-CoV-2. This includes adintrevimab, the parent mAb of pemivibart, and other mAbs that were previously authorized for EUA. There are limitations of the data supporting the benefits of PEMGARDA. Evidence of clinical efficacy for other neutralizing human mAbs against SARS-CoV-2 was based on different populations and SARS-CoV-2 variants that are no longer circulating. Further, the variability associated with cell-based EC50 value determinations, along with limitations related to pharmacokinetic data and efficacy estimates for the mAbs in prior

clinical trials, impact the ability to precisely estimate protective titer ranges. Additionally, certain SARS-CoV-2 viral variants may emerge that have substantially reduced susceptibility to PEMGARDA, and PEMGARDA may not be effective at preventing COVID-19 caused by these SARS-CoV-2 viral variants. PEMGARDA is authorized for use only when the combined national frequency of variants with substantially reduced susceptibility to PEMGARDA is less than or equal to 90%, based on available information including variant susceptibility to PEMGARDA and national variant frequencies.

The emergency use of PEMGARDA is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization revoked sooner. On June 30, 2026, the U.S. Department of Health and Human Services (HHS) announced notice of the termination of the declaration, effective June 29, 2027.

About VYD2311

VYD2311 is a novel monoclonal antibody (mAb) candidate being developed for COVID-19 to continue to address the urgent need for new prophylactic and therapeutic options. The pharmacokinetic profile and antiviral potency of VYD2311 may offer the ability to deliver clinically meaningful titer levels through more patient-friendly means such as an intramuscular route of administration.

VYD2311 was engineered using Invivyd's proprietary integrated technology platform and is the product of serial molecular evolution designed to generate an antibody optimized for neutralizing contemporary virus lineages. VYD2311 leverages the same antibody backbone as pemivibart, Invivyd's investigational mAb granted emergency use authorization in the U.S. for the pre-exposure prophylaxis (PrEP) of symptomatic COVID-19 in certain immunocompromised patients, and adintrevimab, Invivyd's investigational mAb that has a robust safety data package and demonstrated clinically meaningful results in global Phase 2/3 clinical trials for the prevention and treatment of COVID-19.

About DECLARATION

DECLARATION is a Phase 3, randomized, triple-blind, placebo-controlled trial to evaluate VYD2311 efficacy and safety in prevention of symptomatic COVID in a broad population of participants including adults and adolescents both with and without risk factors for progression to severe COVID-19 at three months. Participants will receive either a single dose or monthly doses of VYD2311, each administered via intramuscular (IM) injection, compared to placebo. Total enrollment of the trial is approximately 2,400 participants.

About LIBERTY

LIBERTY is a Phase 3, randomized, double-blind clinical trial to evaluate the safety, serum virus neutralizing antibody responses, and pharmacokinetics of VYD2311, an mRNA COVID vaccine, and co-administered VYD2311 with an mRNA COVID vaccine. Total enrollment of the trial is approximately 210 participants.

About Antibodies for Any Body

Antibodies for Any Body is a national education campaign designed to elevate public understanding of the immune system and explain the role antibodies play in keeping the body healthy. Visit AntibodiesforAnyBody.com to access information and resources and take the Antibodies for Any Body Wellness Assessment to learn more about your health.

About VMS063

VMS063 is a monoclonal antibody candidate engineered via Invivyd's proprietary antibody discovery platform to target a highly conserved protein of a measles virus. The antibody has shown sub-nanomolar potencies across all variants tested in vitro to date.

About VBY329

VBY329 is a novel, potential best-in-class monoclonal antibody (mAb) candidate being developed to prevent Respiratory Syncytial Virus (RSV) among neonates, infants, and children.

About SPEAR Study Group

Invivyd and leading researchers formed the SPEAR (Spike Protein Elimination and Recovery) Study Group to assess the effects of monoclonal antibody (mAb) therapy for Long COVID and COVID-19 Post-Vaccination Syndrome.

About Invivyd

Invivyd, Inc. (Nasdaq: IVVD) is a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2. Invivyd deploys a proprietary integrated technology platform unique in the industry designed to assess, monitor, develop, and adapt to create best in class antibodies. In March 2024, Invivyd received emergency use authorization (EUA) from the U.S. FDA for a monoclonal antibody (mAb) in its pipeline of innovative antibody candidates. Visit <https://invivyd.com/> to learn more.

Trademarks are the property of their respective owners.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "believes," "could," "expects," "estimates," "intends," "plans," "potential," "predicts," "projects," "future," and "target" or similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements include statements concerning, among other things, plans related to the company's research and development activities, and the timing and potential results thereof; expectations regarding the company's clinical trial designs, event accumulation and progress, regulatory pathway, product profile, indication, and administration paradigm for VYD2311, including the company's REVOLUTION clinical program and the timing of expenditures and results related thereto, as well as preparations for the potential commercial launch of VYD2311, if approved; the company's plans to hold a future investor call; expectations regarding the public health landscape and potential advantages of mAbs; the potential of VYD2311 as a novel mAb candidate that may be able to deliver clinically meaningful titer levels through more patient-friendly means; expectations regarding the future termination of the EUA granted by the FDA for PEMGARDA and the transition period; the company's plans and expectations with respect to its other product candidates, including VMS063 and VBY329; the company's business strategies and

objectives; the company's expectations regarding the sufficiency of its current cash and cash equivalents; the potential market size and opportunity for the company's product candidates; the company's future prospects; and other statements that are not historical fact. The company may not actually achieve the plans, intentions, or expectations disclosed in the company's forward-looking statements, and you should not place undue reliance on the company's forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause the company's actual results to differ materially from the results described in or implied by the forward-looking statements, including, without limitation: uncertainties regarding the company's expectations, projections, and estimates regarding future costs and expenses, future revenue, capital requirements, and the availability of and the need for additional financing; uncertainties regarding market acceptance, payor coverage, and reimbursement, or future revenue generated by any authorized or approved product; uncertainties regarding the impact of the future termination of the EUA granted by the FDA for PEMGARDA on the business of the company; uncertainties related to the transition period for PEMGARDA; the ability to maintain a continued acceptable safety, tolerability, and efficacy profile of any product candidate following regulatory authorization or approval; the success of the company's in-house sales force, and the company's ability to maintain and expand sales, marketing, and distribution capabilities to successfully commercialize any authorized or approved product; changes in expected or existing competition; changes in the regulatory environment; the outcome of the company's engagement with regulators; uncertainties related to the regulatory authorization or approval process, and available development and regulatory pathways; whether or not any preclinical candidate identified by the company is determined to be suitable for clinical development; the timing, progress, and results of the company's discovery, preclinical, and clinical development activities; clinical trial event accumulation rates; unexpected safety or efficacy data observed during preclinical studies or clinical trials; the risk that results of nonclinical studies or clinical trials may not be predictive of future results, and interim data are subject to further analysis; the company's ability to generate the data needed to support a potential BLA submission for VYD2311; potential variability in neutralizing activity of product candidates tested in different assays, such as pseudovirus assays and authentic assays; variability of results in models and methods used to predict activity against SARS-CoV-2 variants; whether the epitopes that pemivibart and VYD2311 target remain structurally intact and the company's product candidates are able to demonstrate and sustain neutralizing activity against major SARS-CoV-2 variants, particularly in the face of viral evolution; the risk that a lack of awareness of mAb therapies and regulatory scrutiny of mAb therapies may adversely impact the development or commercial success of the company's product candidates; the company's reliance on third parties; complexities of manufacturing mAb therapies; macroeconomic and political uncertainties; the company's ability to continue as a going concern; and whether the company has adequate funding to meet future operating expenses and capital expenditure requirements. Other factors that may cause the company's actual results to differ materially from those expressed or implied in the forward-looking statements in this press release are described under the heading "Risk Factors" in the company's Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the Securities and Exchange Commission (SEC), and in the company's other filings with the SEC, and in its future reports to be filed with the SEC and available at www.sec.gov. Forward-looking statements contained in this press release are made as of this date, and Invivyd undertakes no duty to update such information whether as a result of new information, future events or otherwise, except as required under applicable law.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference in this press release.

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INVIVYD, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share and per share amounts)

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 160,080	\$ 226,689
Accounts receivable, net ⁽¹⁾	11,222	13,919
Prepaid expenses and other current assets	10,810	6,859
Total current assets	182,112	247,467
Inventory	25,345	25,499
Property and equipment, net	2,183	1,365
Operating lease right-of-use assets	8,067	2,442
Other non-current assets	1,176	110
Total assets	<u>\$ 218,883</u>	<u>\$ 276,883</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 9,486	\$ 13,744
Accrued expenses ⁽²⁾	19,855	19,053
Operating lease liabilities, current	1,616	1,314
Other current liability	71	52
Total current liabilities	31,028	34,163
Operating lease liabilities, non-current	6,775	1,180
Total liabilities	37,803	35,343
Commitments and contingencies		
Stockholders' equity:		
Preferred stock (undesignated), \$0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding at June 30, 2026 and December 31, 2025	—	—
Common stock, \$0.0001 par value; 1,000,000,000 shares authorized, 294,755,090 shares issued and outstanding at June 30, 2026; 281,987,033 shares issued and outstanding at December 31, 2025	29	28
Additional paid-in capital	1,221,362	1,196,036
Accumulated other comprehensive loss	(35)	(41)
Accumulated deficit	(1,040,276)	(954,483)
Total stockholders' equity	181,080	241,540
Total liabilities and stockholders' equity	<u>\$ 218,883</u>	<u>\$ 276,883</u>

(1) Includes an allowance for doubtful accounts of \$199 and \$323 as of June 30, 2026 and December 31, 2025, respectively.

(2) Includes related-party amounts of \$576 and \$703 as of June 30, 2026 and December 31, 2025, respectively.

INVIVYD, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

(In thousands, except share and per share amounts)

	Three Months Ended June 30, 2026	Three Months Ended June 30, 2025	Six Months Ended June 30, 2026	Six Months Ended June 30, 2025
Revenue:				
Product revenue, net	\$ 14,285	\$ 11,786	\$ 28,029	\$ 23,090
Total revenue	14,285	11,786	28,029	23,090
Operating costs and expenses:				
Cost of product revenue ⁽¹⁾	1,273	685	2,305	1,519
Research and development ⁽²⁾	29,367	9,573	60,098	20,214
Selling, general and administrative	29,465	16,588	54,582	33,339
Total operating costs and expenses	60,105	26,846	116,985	55,072
Loss from operations	(45,820)	(15,060)	(88,956)	(31,982)
Other income:				
Other income, net	1,427	400	3,163	1,033
Total other income, net	1,427	400	3,163	1,033
Net loss	(44,393)	(14,660)	(85,793)	(30,949)
Other comprehensive income (loss)				
Unrealized gain (loss), net of tax	2	(26)	6	(34)
Comprehensive loss	\$ (44,391)	\$ (14,686)	\$ (85,787)	\$ (30,983)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.14)	\$ (0.12)	\$ (0.27)	\$ (0.26)
Weighted-average common shares outstanding, basic and diluted	320,435,078	120,016,132	315,082,327	119,950,172

- (1) Includes related-party amounts of \$571 and \$1,121 for the three and six months ended June 30, 2026, respectively, and \$472 and \$924 for the three and six months ended June 30, 2025, respectively.
- (2) Includes related-party amounts of \$1,129 and \$2,255 for the three and six months ended June 30, 2026, respectively, and \$1,140 and \$2,268 for the three and six months ended June 30, 2025, respectively.

