Invivyd Reports Third Quarter 2026 Financial Results and Recent Business Highlights

November 16, 2026

- *DECLARATION Phase 3 clinical trial data on VYD2311 (ibramvibart) to be available imminently, per the Accelerated Approval analysis and regulatory submission plan previously communicated*
- *Updated data timing driven by dialogue between Invivyd and the U.S. FDA 1) to refine details on the Accelerated Approval approach for VYD2311, and 2) to expand the accelerated regulatory approach and enable rapid development of future Invivyd monoclonal antibodies, including Invivyd's measles antibody candidate; further update to be provided with DECLARATION interim analysis data*
- *Achieved Q3 2026 PEMGARDA® (pemivibart) net product revenue of $15.4 million, representing 18% growth versus Q3 2025 net product revenue of $13.1 million*
- *Appointed Chairman Marc W. Elia as Chief Executive Officer*
- *Announced positive topline results from LIBERTY Phase 3 clinical trial, which demonstrated VYD2311 safety and tolerability superior to an mRNA-based COVID-19 vaccine and lack of interference with vaccine-induced neutralizing antibody titers*
- *Announced initiation of FLINTLOCK Phase 2 clinical trial of VYD2311, which will evaluate VYD2311 in adults aged 18-65 years with Long COVID or Post-Vaccination Syndrome, also known as COVID vaccine injury*
- *Investments being made in commercial preparedness for VYD2311; Invivyd plans to host a Medical and Commercial Investor Event in 1H 2027 to describe commercial plans and early expressions of institutional demand*
- *Q3 2026 ending cash and cash equivalents of $126.4 million*

NEW HAVEN, Conn., Nov. 16, 2026 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced financial results for the third quarter ended September 30, 2026, and recent business highlights.

"We are excited about the progress made to advance VYD2311 to meet the urgent need for new options to prevent Americans from getting sick from COVID and suffering from the debilitating impact of Long COVID or COVID vaccine injury," said Marc Elia, Chairman and Chief Executive Officer of Invivyd. "While our DECLARATION data readout timing has been updated as we continued to work with regulators and policymakers on immunization regulation in America broadly, we are pleased that U.S. regulators understand the important role monoclonal antibodies can play in infectious disease going forward. We look forward to providing DECLARATION data and a regulatory update imminently, and we appreciate investor patience as we endeavor to set the stage for anticipated rapid advancement should VYD2311 DECLARATION data demonstrate an attractive clinical profile."

"PEMGARDA's continued growth, even in the face of declining COVID vaccine utilization and announcement of the termination of its Emergency Use Authorization in mid-2027, demonstrates clear demand for monoclonal antibodies," commented Bill Duke, Chief Financial Officer of Invivyd. "With a bolus of REVOLUTION clinical program spend in the rear view at this time, we look forward to a new posture of increased operating efficiency while we work to bring VYD2311 to vulnerable Americans as fast as possible."

Third Quarter 2026 and Recent Company Highlights

PEMGARDA® Commercial Performance & Regulatory Update

- PEMGARDA net product revenue was $15.4 million for the quarter ended September 30, 2026, compared to $13.1 million for the quarter ended September 30, 2025. Growth of 18% was driven primarily 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:

- *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. In September 2026, Invivyd announced positive topline results from LIBERTY demonstrating VYD2311 safety and tolerability superior to an mRNA-based COVID-19 vaccine:
    - VYD2311 met all primary and secondary endpoints comparing VYD2311 to an mRNA-based COVID-19 vaccine, demonstrating VYD2311 safety and tolerability that is clinically and statistically superior to the safety and tolerability of an mRNA-based COVID-19 vaccine.
    - VYD2311 combined with an mRNA-based COVID-19 vaccine demonstrated no interference with vaccine-induced neutralizing titers and instead added substantially to vaccine-induced neutralizing titers.
    - VYD2311 observed profile in LIBERTY indicates high measured neutralizing antiviral titers supporting the target profile for VYD2311 under study in the DECLARATION pivotal clinical study.

- *DECLARATION:* In September 2026, Invivyd announced plans for the DECLARATION Phase 3 clinical trial, with support from the LIBERTY clinical trial and reference to prior Invivyd COVID-19 mAb data, to be the basis of a planned Biologics License Application (BLA) submission for VYD2311 to the FDA under the Accelerated Approval Program. Invivyd plans to conduct a prespecified interim analysis in DECLARATION designed to evaluate serum virus neutralizing antibody titers, pharmacokinetics, immunogenicity, and safety of VYD2311, while keeping blinded the clinical events collected to date. These analyses are intended to support a BLA submission under the Accelerated Approval Program, with the interim data expected imminently. Invivyd plans to continue the DECLARATION study to serve as the confirmatory trial, with DECLARATION continuing to collect RT-PCR-confirmed symptomatic COVID-19 events. Clinical event data from DECLARATION will serve, if the study is positive, as confirmatory evidence for conversion to traditional approval of VYD2311.

- *FLINTLOCK:* 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. In October 2026, Invivyd and the SPEAR Study Group announced initiation of FLINTLOCK.
    - FLINTLOCK Phase 2 clinical trial will evaluate the safety, tolerability, pharmacokinetics, and clinical efficacy of high-dose VYD2311 in adults aged 18-65 years with Long COVID or Post-Vaccination Syndrome, also known as COVID vaccine injury.
    - Design includes VYD2311 administered in three doses to assess the safety and potential clinical benefit of VYD2311 treatment versus placebo over 90 days.

Measles

- In October 2026, Invivyd presented VMS063, a novel, potential first-and best-in-class monoclonal antibody investigational candidate for the treatment and prevention of measles, at IDWeek 2026™. VMS063 preclinical data has demonstrated potent in vitro antiviral activity against contemporary measles virus variants and attractive biophysical properties supporting its potential utility for both treatment and prevention of measles. Invivyd is scaling up production toward clinical development in 2027.

Corporate Updates

- In September 2026, Invivyd announced the appointment of Marc Elia, Chairman of Invivyd's Board of Directors (the Board), as Chief Executive Officer of Invivyd. In addition, Invivyd announced Ajay Royan, Founder of Mithril Capital, a founding, long-term investor of Invivyd, and a member of the Board, was appointed as Lead Independent Director of the Board, and Ian Sheffield was appointed to the Board as an independent director.

Third Quarter 2026 Financial Results

- **Revenue:** Reported Q3 2026 PEMGARDA net product revenue of $15.4 million, compared to $13.1 million in Q3 2025, representing an 18% increase.
- **Cash Position:** Cash and cash equivalents were $126.4 million as of September 30, 2026.
- **R&D Expenses:** R&D expenses were $18.7 million for the quarter ended September 30, 2026, compared to $8.0 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 $30.3 million for the quarter ended September 30, 2026, compared to $15.0 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 $33.5 million for the quarter ended September 30, 2026, compared to $10.5 million for the comparable period in 2025. Basic and diluted net loss per share was $0.10 for the quarter ended September 30, 2026, compared to $0.06 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 is 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 study 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 was approximately 210 participants.

About FLINTLOCK
FLINTLOCK is a Phase 2, randomized, double-blind, placebo-controlled, proof-of-concept study being conducted to investigate the safety, tolerability, pharmacokinetics, clinical activity, immunogenicity, and SARS-CoV-2 neutralizing antibody response of VYD2311. VYD2311 will be administered first as a loading dose via intravenous infusion on Day 1 followed by additional intramuscular injections on Day 30 and Day 60 in adults aged 18-65 years with a confirmed diagnosis of Long COVID or Post-Vaccination Syndrome (PVS), with two or more symptoms, with or without SARS-CoV-2 spike antigen that are present ≥6 months after having a COVID-19 infection or vaccination. Total enrollment of the trial is approximately 130 participants.

About VMS063
VMS063 is a novel, highly potent, half-life-extended, high resistance barrier measles monoclonal antibody candidate engineered via Invivyd's proprietary antibody discovery platform to target a highly conserved protein of measles virus. VMS063 targets the measles Fusion (F) protein and is designed to lock the trimeric measles Fusion protein into a pre-fusion configuration, thereby preventing cell entry, similar to approved pediatric respiratory syncytial virus (RSV) monoclonal antibodies. VMS063 could be the first precision therapy for measles, as well as a potentially important passive preventive option to supplement or enhance measles vaccination.

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.

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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," "future," "intends," "plans," "potential," "predicts," "projects," 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, patient populations, and administration paradigm for VYD2311, including the company's REVOLUTION clinical program and the timing of results and expenditures related thereto; the company's plans to submit a BLA for VYD2311 to the FDA under the Accelerated Approval Program; the company's plans to hold a future investor event; expectations regarding the public health landscape and the potential role mAbs can play in infectious disease; 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 the potential utility of VMS063 as a novel, potential first- and best-in class mAb candidate being developed for the treatment and prevention of measles; the company's strategies and objectives; the company's expectations regarding operational efficiencies; 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, including eligibility for any expedited regulatory review and approval approaches; 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; uncertainties regarding clinical trial event accumulation rates and statistical powering; 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, and uncertainties regarding the FDA's acceptance and review of any such BLA submission; the predictability of clinical success of the company's product candidates based on neutralizing activity in nonclinical studies; 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, and its Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, each 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)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 126,398	$ 226,689
Accounts receivable, net[1]	12,194	13,919
Prepaid expenses and other current assets	9,254	6,859
Total current assets	147,846	247,467
Inventory	25,232	25,499
Property and equipment, net	2,478	1,365
Operating lease right-of-use assets	7,642	2,442
Other non-current assets	707	110
Total assets	$ 183,905	$ 276,883
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable[2]	$ 6,370	$ 13,744
Accrued expenses[3]	18,713	19,053
Operating lease liabilities, current	1,640	1,314
Other current liability	91	52
Total current liabilities	26,814	34,163
Operating lease liabilities, non-current	6,608	1,180
Total liabilities	33,422	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 September 30, 2026 and December 31, 2025	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 295,632,147 shares issued and outstanding at September 30, 2026; 281,987,033 shares issued and outstanding at December 31, 2025	29	28
Additional paid-in capital	1,224,233	1,196,036
Accumulated other comprehensive loss	(35)	(41)
Accumulated deficit	(1,073,744)	(954,483)
Total stockholders' equity	150,483	241,540
Total liabilities and stockholders' equity	$ 183,905	$ 276,883

(1) Includes an allowance for doubtful accounts of $49 and $323 as of September 30, 2026 and December 31, 2025, respectively.
(2) Includes related-party amounts of $2,000 and $0 as of September 30, 2026 and December 31, 2025, respectively.
(3) Includes related-party amounts of $626 and $703 as of September 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 September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Revenue:				
Product revenue, net	$ 15,449	$ 13,129	$ 43,478	$ 36,219
Total revenue	15,449	13,129	43,478	36,219
Operating costs and expenses:				
Cost of product revenue[1]	1,043	1,088	3,348	2,607
Research and development[2]	18,736	8,046	78,834	28,260
Selling, general and administrative	30,349	15,018	84,931	48,357
Total operating costs and expenses	50,128	24,152	167,113	79,224
Loss from operations	(34,679)	(11,023)	(123,635)	(43,005)
Other income:				
Other income, net	1,211	553	4,374	1,586
Total other income, net	1,211	553	4,374	1,586
Net loss	(33,468)	(10,470)	(119,261)	(41,419)
Other comprehensive income (loss)				
Unrealized gain (loss), net of tax	—	(2)	6	(36)
Comprehensive loss	$ (33,468)	$ (10,472)	$ (119,255)	$ (41,455)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.10)	$ (0.06)	$ (0.38)	$ (0.30)
Weighted-average common shares outstanding, basic and diluted	322,431,421	170,169,865	317,558,945	136,874,025

(1) Includes related-party amounts of $618 and $1,739 for the three and nine months ended September 30, 2026, respectively, and $525 and $1,449 for the three and nine months ended September 30, 2025, respectively.
(2) Includes related-party amounts of $1,133 and $3,388 for the three and nine months ended September 30, 2026, respectively, and $1,158 and $3,426 for the three and nine months ended September 30, 2025, respectively.