Invivyd Reports Third Quarter 2025 Financial Results and Recent Business Highlights

November 6, 2025

- *PEMGARDA® (pemivibart) net product revenue of $13.1 million reported for Q3 2025, representing 41% growth year-over-year and 11% growth quarter-over-quarter*
- *October 2025 ending cash and cash equivalents of over $100 million; ended Q3 2025 with $85.0 million in cash and cash equivalents after closing of $57.5 million public offering in August 2025, with additional $29.8 million gross proceeds from usage of at-the-market (ATM) offering facility in October 2025*
- *Announced U.S. IND clearance and alignment with U.S. FDA on pivotal clinical program for VYD2311, a vaccine-alternative antibody to prevent COVID*
- *REVOLUTION, Invivyd's development program for VYD2311, comprises the DECLARATION (safety and efficacy vs. placebo) and LIBERTY (exploratory safety head-to-head and combination with mRNA-based COVID vaccination) clinical trials, which are expected to begin around year-end 2025; top-line data anticipated mid-2026*

NEW HAVEN, Conn., Nov. 06, 2025 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced financial results for the quarter ended September 30, 2025, and provided recent business highlights.

"With a strengthened balance sheet and a clear path forward for VYD2311 with recent IND clearance and U.S. Food and Drug Administration (FDA) alignment, Invivyd is well-poised to provide Americans with antibody protection as an alternative to COVID vaccination," said Marc Elia, Chairman of the Board of Directors at Invivyd. "Given the current unmet need, we are preparing for our pivotal studies and potential commercial launch of VYD2311 with urgency and to secure Invivyd's place as the leader in providing antibodies to prevent people from becoming sick with COVID. We are also looking at pathogens beyond COVID because humankind may benefit from additional, high quality immune power in preventing these illnesses."

"We are pleased that third quarter revenue growth, combined with controlled operating expenses, has set us up to invest at the appropriate level for our future growth," said Bill Duke, Chief Financial Officer of Invivyd. "Our past discipline and learnings from our commercial organization will enable us to further invest in VYD2311, including upcoming initiation of our REVOLUTION pivotal clinical program and execution of a go-to-market strategy and related commercial build-out to prepare for launch, if approved."

Recent Business Highlights

- **Commercial Execution**
  - PEMGARDA® (pemivibart) uptake continues to grow among healthcare providers caring for immunocompromised patients, supported by Invivyd's in-house sales force and expanded field presence across key specialties.
- **Ongoing Variant Coverage**
  - In August 2025, Invivyd announced positive, clinically meaningful in vitro neutralization data for PEMGARDA (pemivibart) and VYD2311 against currently dominant and growing XFG variant of SARS-CoV-2. Notably, and consistent with all dominant variants for the past three years, XFG did not generate any meaningful change to the in vitro neutralization activity of pemivibart or VYD2311, as the epitopes targeted by pemivibart and VYD2311 remain structurally intact.
- **Clinical & Regulatory Developments**
  - In October 2025, Invivyd announced that the FDA cleared the company's IND application and provided feedback to advance the company's REVOLUTION clinical program, Invivyd's development program for VYD2311, a vaccine alternative monoclonal antibody candidate for the prevention of COVID. The REVOLUTION clinical program includes the DECLARATION and LIBERTY clinical trials.
    - DECLARATION is the company's Biologics License Application (BLA)-enabling Phase 3, randomized, triple-blind, placebo-controlled pivotal clinical trial to evaluate the safety and efficacy of VYD2311 for the prevention of symptomatic COVID, at three months, from a single intramuscular (IM) dose of VYD2311, with longer-term protection anticipated. A second VYD2311 arm will evaluate monthly IM doses to demonstrate the safety and efficacy of more frequent dosing to support individual choice should at-risk persons wish periodic extra protection. Total expected enrollment in the DECLARATION clinical trial is 1,770 people.
    - LIBERTY is designed as a Phase 3, randomized, pooled-vaccine, double-blind clinical trial to evaluate head-to-head safety and tolerability and co-administration interaction of VYD2311 with approved mRNA-based COVID vaccines in adults; final alignment with the FDA on combination design with

vaccination expected shortly. Total expected enrollment in the LIBERTY clinical trial is 210 people.

- **Pipeline Expansion**
  - Invivyd has initiated discovery efforts to assess pipeline expansion beyond SARS-CoV-2, including potential targets such as respiratory syncytial virus (RSV) and measles.

- **Corporate and Financial Updates**
  - In September 2025, Invivyd announced appointment of Paul B. Bolno, M.D., to its Board of Directors as well as Kristie Kuhl as Chief Communications Officer.
  - In August 2025, Invivyd announced closing of an underwritten public offering of its common stock and pre-funded warrants. The gross proceeds from the offering were approximately $57.5 million, before deducting underwriting discounts and commissions and offering expenses payable by Invivyd. The financing was led by RA Capital Management and Janus Henderson Investors, with participation from multiple other new and existing healthcare focused investors.
  - In July 2025, Invivyd and leading researchers formed the SPEAR (Spike Protein Elimination and Recovery) Study Group to assess the effects of monoclonal antibody therapy for Long COVID and COVID-19 Post-Vaccination Syndrome.

Third Quarter 2025 Financial Results

- **Revenue:** Reported Q3 2025 PEMGARDA net product revenue of $13.1 million, as compared to $9.3 million in Q3 2024 and $11.8 million in Q2 2025.
- **Cash Position:** Cash and cash equivalents were $85.0 million as of September 30, 2025.
- **Research & Development (R&D) Expenses (including In-Process R&D):** R&D expenses were $8.0 million for the quarter ended September 30, 2025, compared to $57.9 million for the comparable period of 2024. This decrease is primarily attributable to a decrease in commercial manufacturing costs of VYD2311, a decrease in clinical trial costs related to our CANOPY Phase 3 clinical trial of pemivibart and a decrease in non-clinical R&D costs.
- **Selling, General & Administrative (SG&A) Expenses:** SG&A expenses were $15.0 million for the quarter ended September 30, 2025, compared to $13.0 million for the comparable period of 2024. This increase is primarily attributable to higher personnel-related costs, partially offset by decreased sales and marketing costs.
- **Net Loss and Net Loss per Share:** Net loss was $10.5 million for the quarter ended September 30, 2025, compared to $60.7 million for the comparable period in 2024. Basic and diluted net loss per share was $0.06 for the quarter ended September 30, 2025, compared to $0.51 for the comparable period in 2024. For the quarter ended September 30, 2025, the 21,342,442 shares of common stock issuable upon exercise of outstanding pre-funded warrants were included as outstanding common stock for purposes of the calculation of net loss per share.

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 treatment of COVID-19, treatment of Long COVID, or 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.

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 declaration is terminated or authorization revoked sooner. 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**.**

About CANOPY

The CANOPY Phase 3 clinical trial was designed to evaluate the safety and tolerability of pemivibart and to assess immunobridging from pemivibart to certain historical data from the company's previous Phase 2/3 clinical trial of adintrevimab (ADG20) for the prevention of symptomatic COVID-19 (EVADE). Additionally, there were pre-specified exploratory endpoints through three, six and twelve months to evaluate clinical efficacy of pemivibart compared to placebo in the prevention of RT-PCR-confirmed symptomatic COVID-19. The latest analysis from the Phase 3 CANOPY clinical trial included 365-day data. The CANOPY clinical trial enrolled participants in two cohorts: Cohort A was a single-arm, open-label trial in adults with moderate-to-severe immune compromise including complex underlying medical conditions. Cohort B was a randomized, placebo-controlled cohort that enrolled adults without moderate-to-severe immune compromise at risk of acquiring COVID-19 due to regular unmasked face-to-face interactions in indoor settings.

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 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.

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," "potential," "predicts," "projects," and "future" 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; the potential of Invivyd to provide Americans with antibody protection as an alternative to COVID vaccination; expectations regarding the company's clinical trial designs and enrollment, regulatory pathway, product profile, indication and potential administration paradigm for VYD2311, as well as the go-to-market strategy and related commercial build-out to prepare for launch of VYD2311, if approved; beliefs about the company's market position; the anticipated focus and goals of the SPEAR Study Group; the ongoing in vitro neutralizing activity of PEMGARDA against dominant SARS-CoV-2 variants; the potential of PEMGARDA as a mAb for pre-exposure prophylaxis (prevention) of COVID-19 in certain immunocompromised persons; the potential of VYD2311 as a novel mAb

candidate that may be able to deliver clinically meaningful titer levels through more patient-friendly means; the company's devotion to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2; potential pipeline expansion beyond SARS-CoV-2, including potential targets such as RSV and measles, and expected announcements related thereto; the company's business strategies and objectives, and ability to execute on them; 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; whether the company's cash and cash equivalents are sufficient to support its operating plan for as long as anticipated; uncertainties regarding market acceptance, payor coverage and reimbursement, or future revenue generated by PEMGARDA; how long the EUA granted by the FDA for PEMGARDA will remain in effect and whether such EUA is revised or revoked by the FDA; 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 company's ability to maintain and expand sales, marketing and distribution capabilities to successfully commercialize any authorized or approved product candidates; 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; the timing, progress and results of the company's discovery, preclinical and clinical development activities, including the initiation of the DECLARATION clinical trial, and finalization and initiation of other aspects of the REVOLUTION clinical program, such as the LIBERTY clinical trial, subject to final alignment with the FDA; clinical trial site activation or enrollment rates; unexpected safety or efficacy data observed during preclinical studies or clinical trials; the predictability of clinical success of the company's product candidates based on neutralizing activity in nonclinical studies; 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; whether 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 company's reliance on third parties; complexities of manufacturing mAb therapies, and availability of quantities of commercial product in the future, if authorized or approved; 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, 2024 and the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, 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.

Contacts:
Media Relations
(781) 208-0160
media@invivyd.com

Investor Relations
(781) 208-1747
investors@invivyd.com

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

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 84,967	$ 69,349
Accounts receivable, net	9,852	10,906
Prepaid expenses and other current assets	14,950	20,426
Total current assets	109,769	100,681
Inventory	25,395	25,907
Property and equipment, net	1,260	1,508

Operating lease right-of-use assets	2,728	1,385
Other non-current assets	6	34
Total assets	$ 139,158	$ 129,515
Liabilities, Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 18,104	$ 10,448
Accrued expenses [1]	25,277	50,197
Operating lease liabilities	1,083	1,304
Other current liability	32	27
Total current liabilities	44,496	61,976
Operating lease liabilities, non-current	1,594	—
Total liabilities	46,090	61,976
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, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 214,409,450 shares issued and outstanding at September 30, 2025; 119,835,162 shares issued and outstanding at December 31, 2024	22	12
Additional paid-in capital	1,036,500	969,526
Accumulated other comprehensive loss	(41)	(5)
Accumulated deficit	(943,413)	(901,994)
Total stockholders' equity	93,068	67,539
Total liabilities, preferred stock and stockholders' equity	$ 139,158	$ 129,515

(1) Includes related-party amounts of $716 and $1,274 as of September 30, 2025 and December 31, 2024, 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, 2025	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Revenue:				
Product revenue, net	$ 13,129	$ 9,300	$ 36,219	$ 11,564
Total revenue	13,129	9,300	36,219	11,564
Operating costs and expenses:				
Cost of product revenue [1]	1,088	806	2,607	894
Research and development [2]	8,046	57,850	28,260	119,344
Selling, general and administrative	15,018	12,955	48,357	48,973
Total operating costs and expenses	24,152	71,611	79,224	169,211
Loss from operations	(11,023)	(62,311)	(43,005)	(157,647)
Other income:				
Other income, net	553	1,572	1,586	6,165

Total other income, net	553	1,572	1,586	6,165
Net loss	(10,470)	(60,739)	(41,419)	(151,482)
Other comprehensive income (loss)				
Unrealized (loss), net of tax	(2)	(6)	(36)	(5)
Comprehensive loss	$ (10,472)	$ (60,745)	$ (41,455)	$ (151,487)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.06)	$ (0.51)	$ (0.30)	$ (1.28)
Weighted-average common shares outstanding, basic and diluted	170,169,865	119,495,284	136,874,025	118,163,599

(1) Includes related-party amounts of $525 and $1,449 for the three and nine months ended September 30, 2025, respectively, and related-party amounts of $463 for both the three and nine months ended September 30, 2024.
(2) Includes related-party amounts of $1,158 and $3,426 for the three and nine months ended September 30, 2025, respectively, and $1,133 and $3,399 for the three and nine months ended September 30, 2024, respectively.