



Nuvation Bio Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Business Update

Successfully started 216 patients on IBTROZI® (taletrectinib) in the fourth quarter of 2025, for a total of 432 new patient starts since launch in the second half of June 2025

Entered into exclusive licensing and collaboration agreement with Eisai on January 11, 2026, for taletrectinib in Europe and additional countries outside U.S., China and Japan

Published positive Phase 2 study results for safusidenib demonstrating durable responses for the treatment of grade 2 IDH1-mutant glioma

Strong balance sheet with cash, cash equivalents, and marketable securities of \$529.2 million as of December 31, 2025

Company to host a conference call today at 4:30 pm ET

NEW YORK—March 2, 2026— Nuvation Bio Inc. (NYSE: NUVB), a global oncology company focused on tackling some of the toughest challenges in cancer treatment, today reported financial results for the fourth quarter and full year ended December 31, 2025, and provided a business update.

“We ended our transformational 2025 with a strong fourth quarter that underscored IBTROZI’s rapid adoption, and we believe our medicine is becoming the new standard of care for people living with advanced ROS1+ NSCLC across treatment lines. In 2026, we look forward to further building upon our successful U.S. launch, and partnering closely with Eisai to bring IBTROZI to more patients around the globe,” said David Hung, M.D., Founder, President, and Chief Executive Officer of Nuvation Bio. “We are also excited and eager to progress our promising pipeline, with safusidenib now being studied in the pivotal Phase 3 SIGMA trial across those living with high-risk and high-grade IDH1-mutant glioma where significant needs exist for these patients. Lastly, we continue to evaluate additional internal preclinical candidates and external business development opportunities in hopes of furthering our mission to tackle some of the toughest challenges in cancer treatment.”

Fourth Quarter 2025 and Recent Corporate Highlights:

IBTROZI® (taletrectinib), ROS1 inhibitor: *Advanced ROS1+ NSCLC*

- In the fourth quarter of 2025, 216 new patients started treatment on IBTROZI for advanced ROS1-positive (ROS1+) non-small cell lung cancer (NSCLC), reflecting the high rate of adoption and confidence in IBTROZI among healthcare professionals and patients.
- With 432 new patients started since launch in the second half of June 2025, the treatment adoption rate is approximately six times greater than that of prior recent ROS1 tyrosine kinase inhibitor (TKI) launches based on IQVIA data.
- On January 11, 2026, the Company entered an exclusive license and collaboration agreement with Eisai Co., Ltd. to develop, register and commercialize taletrectinib for the treatment of ROS1+ NSCLC in Europe, the Middle East, North Africa, Russia, Turkey, Canada, Australia, New Zealand, Singapore, the Philippines, Indonesia, Thailand, Malaysia, Vietnam, and India.

- In the fourth quarter of 2025, the Company received a \$25 million milestone payment from Nippon Kayaku as a result of establishing the reimbursement price in Japan.
- In October 2025, the Company presented clinical data from the pivotal TRUST-II study evaluating IBTROZI in patients previously treated with entrectinib, a brain-penetrant ROS1 therapy at the European Society of Medical Oncology (ESMO) Congress 2025.
 - IBTROZI demonstrated a confirmed overall response rate of 80% in 10 patients whose tumors progressed following treatment with entrectinib.

Safusidenib, mIDH1 inhibitor: IDH1-mutant glioma

- In December 2025, the Company announced the publication of positive results from a Phase 2 study of safusidenib in patients with chemotherapy- and radiotherapy-naïve grade 2 *IDH1*-mutant gliomas. The findings were first published online on November 8, 2025, in *Neuro-Oncology*.
 - Safusidenib demonstrated durable responses, with an ORR of 44% and 88% of patients were progression-free at 24 months.
 - The findings supported favorable interactions with the U.S. Food and Drug Administration (FDA) and the now finalized protocol amendment making the SIGMA study (G203) a Phase 3, pivotal trial evaluating safusidenib maintenance treatment in high-risk and high-grade IDH1-mutant gliomas. The study now also includes an additional exploratory cohort in grade 3 oligodendroglioma.
- In October 2025, the Company enrolled the first patient in the global SIGMA study (G203).

Fourth Quarter and Full Year 2025 Financial Results

As of December 31, 2025, Nuvation Bio had cash, cash equivalents, and marketable securities of \$529.2 million.

Product Revenue, Net

To date, our only source of product revenue has been from the U.S. sales of IBTROZI. We began distributing IBTROZI to our U.S. customers in June 2025. Net product revenue from U.S. sales of IBTROZI was approximately \$15.7 million and \$24.7 million for the three and twelve months ended December 31, 2025, respectively.

Collaboration and License Agreements Revenue

For the three months ended December 31, 2025, collaboration and license agreements revenue was \$26.2 million, compared to \$5.7 million for the three months ended December 31, 2024. The increase is primarily due to a \$25 million milestone payment from Nippon Kayaku as a result of establishment of the reimbursement price for IBTROZI in Japan in Q4, offset by a \$4.5 million decrease in research and development service revenue under the collaboration agreement with Innovent. Taletrectinib was included in China's National Reimbursement Drug List effective January 1, 2026.

For the twelve months ended December 31, 2025, collaboration and license agreements revenue was \$38.2 million, compared to \$7.9 million for 2024. The increase is primarily due to a \$19.1 million increase in license revenue and a \$6.3 million increase in research and development service revenue as a result of milestone payment from Nippon Kayaku for the establishment of the reimbursement price in Japan in December 2025, a \$3.6 million increase in product supply revenue, and a \$1.3 million increase in royalty revenue.

Research and Development Expenses

For the three months ended December 31, 2025, research and development expenses were \$34.3 million, compared to \$29.3 million for the three months ended December 31, 2024. The increase was due to an \$11.4 million increase in third-party costs related to clinical studies, offset by a \$2.4 million decrease in personnel-related costs because employee compensation and benefit costs directly related to commercial drug production were capitalized into inventory, as well as a \$4.0 million decrease in regulatory milestone payments to Daiichi.

For the twelve months ended December 31, 2025, research and development expenses were \$115.1 million, compared to \$99.1 million for the twelve months ended December 31, 2024. The increase was primarily due to a \$7.8 million increase in salaries and other benefits driven by the increase in headcount and stock-based compensation primarily related to one-time charge for the vesting of performance-based awards upon receiving U.S. FDA approval of IBTROZI, a \$12.1 million increase in third-party costs related to clinical studies, and a \$0.1 million increase in amortization of assembled workforce, offset by a \$4.0 million decrease in regulatory milestone payments to Daiichi.

Acquired In-process Research and Development Expenses

On April 9, 2024, as a result of the acquisition of AnHeart Therapeutics Ltd., we recorded a \$425.1 million charge representing an acquired in-process research and development asset with no alternative future use in acquired in-process research and development expenses.

Selling, General and Administrative Expenses

For the three months ended December 31, 2025, selling, general, and administrative expenses were \$40.3 million, compared to \$26.1 million for the three months ended December 31, 2024. The increase was due to a \$7.3 million increase in personnel-related costs as a result of the increase in headcount, a \$5.9 million increase in sales and marketing expenses, a \$2.1 million increase in legal fees, offset by a \$0.4 million decrease in professional fees, and a \$0.7 million decrease in foreign currency impact.

For the twelve months ended December 31, 2025, selling, general, and administrative expenses were \$151.6 million, compared to \$69.2 million for the twelve months ended December 31, 2024. The increase was due to a \$39.4 million increase in personnel-related costs as a result of the increase in headcount and stock-based compensation primarily related to one-time charge for the vesting of performance-based awards upon receiving U.S. FDA approval of IBTROZI, a \$41.0 million increase in sales and marketing expenses, a \$3.1 million increase in legal fees, a \$0.1 million increase in professional fees and a \$0.3 million increase in other expenses, offset by a \$1.5 million decrease in foreign currency impact.

Net loss

For the three months ended December 31, 2025, Nuvation Bio reported a net loss of \$36.6 million, or \$(0.11) per share. The net loss for the comparable period in 2024 was \$49.4 million, or \$(0.15) per share.

For the twelve months ended December 31, 2025, Nuvation Bio reported a net loss of \$204.6 million, or \$(0.60) per share. The net loss for the comparable period in 2024 was \$567.9 million, or \$(2.11) per share.

Conference Call and Webcast

Nuvation Bio will host a conference call and webcast today, March 2, 2026, at 4:30 pm ET to discuss its financial results for the fourth quarter and full year of 2025 and provide business updates.

Investors and the general public are invited to listen to the live webcast and may register on the [Investor Relations](#) section of the Nuvation Bio website. To access the live conference call, participants can dial +1 833-470-1428 (U.S. toll-free) and enter access code 833155. An archived recording will be available on Nuvation Bio's website for 90 days following the event.

About ROS1+ NSCLC

Each year, more than one million people globally are diagnosed with non-small cell lung cancer (NSCLC), the most common form of lung cancer. It is estimated that approximately 2% of patients with NSCLC have ROS1+ disease. About 35% of patients newly diagnosed with metastatic ROS1+ NSCLC have tumors that have spread to their brain. The brain is also the most common site of disease progression, with about 50% of previously treated patients developing central nervous system (CNS) metastases.

About IBTROZI

IBTROZI is an oral, potent, CNS-active, selective, next-generation ROS1 inhibitor therapy. On June 11, 2025, following Priority Review and Breakthrough Therapy designations for both TKI-naïve and TKI-pretreated disease, the U.S. Food and Drug Administration (FDA) approved IBTROZI for the treatment of adult patients with locally advanced or metastatic ROS1+ NSCLC. Learn more at [IBTROZI.com](#).

About the TRUST Clinical Program

The TRUST clinical program comprises three registrational studies evaluating the safety and efficacy of IBTROZI. TRUST-I ([NCT04395677](#)) and TRUST-II ([NCT04919811](#)) are Phase 2 single-arm studies evaluating IBTROZI for the treatment of adults with advanced ROS1+ NSCLC in China (N=173) and globally (N=189), respectively. The primary endpoint of both studies is confirmed objective response rate (cORR) as assessed by an independent review committee. TRUST-IV ([NCT07154706](#)) is a Phase 3 placebo-controlled study evaluating IBTROZI for the adjuvant treatment of adults with resected early-stage ROS1+ NSCLC. The study will enroll approximately 180 patients in the U.S., Canada, Europe, Japan and China. The primary endpoint is disease-free survival as determined by investigator, and the primary completion date is estimated to be in 2030. Nuvation Bio is also sponsoring TRUST-III ([NCT06564324](#)), a confirmatory randomized Phase 3 study evaluating IBTROZI versus crizotinib in 138 patients in China with advanced ROS1+ NSCLC who have not previously received ROS1 TKIs.

Indication

IBTROZI is indicated for the treatment of adult patients with locally advanced or metastatic ROS1+ non-small cell lung cancer (NSCLC).

IMPORTANT SAFETY INFORMATION FOR IBTROZI® (taletrectinib)

WARNINGS AND PRECAUTIONS

Hepatotoxicity: Hepatotoxicity, including drug-induced liver injury and fatal adverse reactions, can occur. 88% of patients experienced increased AST, including 10% Grade 3/4. 85% of patients experienced increased ALT, including 13% Grade 3/4. Fatal liver events occurred in 0.6% of patients. Median time to first onset of AST or ALT elevation was 15 days (range: 3 days to 20.8 months).

Increased AST or ALT each led to dose interruption in 7% of patients and dose reduction in 5% and 9% of patients, respectively. Permanent discontinuation was caused by increased AST, ALT, or bilirubin each in 0.3% and by hepatotoxicity in 0.6% of patients.

Concurrent elevations in AST or ALT ≥ 3 times the ULN and total bilirubin ≥ 2 times the ULN, with normal alkaline phosphatase, occurred in 0.6% of patients.

Interstitial Lung Disease (ILD)/Pneumonitis: Severe, life-threatening, or fatal ILD or pneumonitis can occur. ILD/pneumonitis occurred in 2.3% of patients, including 1.1% Grade 3/4. One fatal ILD case occurred at the 400 mg daily dose. Median time to first onset of ILD/pneumonitis was 3.8 months (range: 12 days to 11.8 months).

ILD/pneumonitis led to dose interruption in 1.1% of patients, dose reduction in 0.6% of patients, and permanent discontinuation in 0.6% of patients.

QTc Interval Prolongation: QTc interval prolongation can occur, which can increase the risk for ventricular tachyarrhythmias (e.g., torsades de pointes) or sudden death. IBTROZI prolongs the QTc interval in a concentration-dependent manner.

In patients who received IBTROZI and underwent at least one post baseline ECG, QTcF increase of >60 msec compared to baseline and QTcF >500 msec occurred in 13% and 2.6% of patients, respectively. 3.4% of patients experienced Grade ≥ 3 . Median time from first dose of IBTROZI to onset of ECG QT prolongation was 22 days (range: 1 day to 38.7 months). Dose interruption and dose reduction each occurred in 2.8% of patients.

Significant QTc interval prolongation may occur when IBTROZI is taken with food, strong and moderate CYP3A inhibitors, and/or drugs with a known potential to prolong QTc. Administer IBTROZI on an empty stomach. Avoid concomitant use with strong and moderate CYP3A inhibitors and/or drugs with a known potential to prolong QTc.

Hyperuricemia: Hyperuricemia can occur and was reported in 14% of patients, with 16% of these requiring urate-lowering medication without pre-existing gout or hyperuricemia. 0.3% of patients experienced Grade ≥ 3 . Median time to first onset was 2.1 months (range: 7 days to 35.8 months). Dose interruption occurred in 0.3% of patients.

Myalgia with Creatine Phosphokinase (CPK) Elevation: Myalgia with or without CPK elevation can occur. Myalgia occurred in 10% of patients. Median time to first onset was 11 days (range: 2 days to 10 months).

Concurrent myalgia with increased CPK within a 7-day time period occurred in 0.9% of patients. Dose interruption occurred in 0.3% of patients with myalgia and concurrent CPK elevation.

Skeletal Fractures: IBTROZI can increase the risk of fractures. ROS1 inhibitors as a class have been associated with skeletal fractures. 3.4% of patients experienced fractures, including 1.4% Grade 3. Some fractures occurred in the setting of a fall or other predisposing factors. Median time to first onset of fracture was 10.7 months (range: 26 days to 29.1 months). Dose interruption occurred in 0.3% of patients.

Embryo-Fetal Toxicity: Based on literature, animal studies, and its mechanism of action, IBTROZI can cause fetal harm when administered to a pregnant woman.

ADVERSE REACTIONS

Among patients who received IBTROZI, the most frequently reported adverse reactions ($\geq 20\%$) were diarrhea (64%), nausea (47%), vomiting (43%), dizziness (22%), rash (22%), constipation (21%), and fatigue (20%).

The most frequently reported Grade 3/4 laboratory abnormalities ($\geq 5\%$) were increased ALT (13%), increased AST (10%), decreased neutrophils (5%), and increased creatine phosphokinase (5%).

DRUG INTERACTIONS

- **Strong and Moderate CYP3A Inhibitors/CYP3A Inducers and Drugs that Prolong the QTc Interval:** Avoid concomitant use.
- **Gastric Acid Reducing Agents:** Avoid concomitant use with PPIs and H2 receptor antagonists. If an acid-reducing agent cannot be avoided, administer locally acting antacids at least 2 hours before or 2 hours after taking IBTROZI.

OTHER CONSIDERATIONS

- **Pregnancy:** Please see important information in Warnings and Precautions under Embryo-Fetal Toxicity.
- **Lactation:** Advise women not to breastfeed during treatment and for 3 weeks after the last dose.
- **Effect on Fertility:** Based on findings in animals, IBTROZI may impair fertility in males and females. The effects on animal fertility were reversible.
- **Pediatric Use:** The safety and effectiveness of IBTROZI in pediatric patients has not been established.
- **Photosensitivity:** IBTROZI can cause photosensitivity. Advise patients to minimize sun exposure and to use sun protection, including broad-spectrum sunscreen, during treatment and for at least 5 days after discontinuation.

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

About *IDH1*-Mutant Glioma

Gliomas are the most common type of brain cancer in adults worldwide. In the U.S., nearly 2,400 people are diagnosed with *IDH1*-mutant gliomas each year. Most patients are diagnosed in their 30s and 40s. While patients with *IDH1* mutations generally have longer survival times than those with wild-type *IDH1*, gliomas are not currently curable and prognosis worsens for those with high grade tumors.

About Safusidenib

Safusidenib is a novel, oral, potent, brain-penetrant, targeted inhibitor of mutant *IDH1*. In Phase 1 and 2 clinical studies, safusidenib was well-tolerated and demonstrated anti-tumor activity and high blood-brain barrier penetration.

About Nuvation Bio

Nuvation Bio is a global oncology company focused on tackling some of the toughest challenges in cancer treatment with the goal of developing therapies that create a profound, positive impact on patients' lives. Our diverse pipeline includes talretrectinib (IBTROZI[®]), a next-generation ROS1 inhibitor; safusidenib, a brain-penetrant IDH1 inhibitor; and an innovative drug-drug conjugate (DDC) program.

Nuvation Bio was founded in 2018 by biopharma industry veteran David Hung, M.D., who previously founded Medivation, Inc., which brought to patients one of the world’s leading prostate cancer medicines. Nuvation Bio has offices in New York, San Francisco, Boston, and Shanghai. For more information, visit www.nuvationbio.com or follow the company on [LinkedIn](#) and X ([@nuvationbioinc](#)).

Forward-Looking Statements

Certain statements included in this press release that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements are sometimes accompanied by words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “should,” “would,” “plan,” “predict,” “potential,” “seem,” “seek,” “future,” “outlook” and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements about IBTROZI and safusidenib’s therapeutic and commercial potential, IBTROZI becoming the new standard of care in advanced ROS1+ NSCLC across treatment lines, bringing IBTROZI to more patients worldwide, the need for new therapeutic options in IDH1-mutant gliomas, and our evaluation of additional preclinical candidates and external business development opportunities. These statements are based on various assumptions, whether or not identified in this press release, and on the current expectations of the management team of Nuvation Bio and are not predictions of actual performance. These forward-looking statements are subject to a number of risks and uncertainties that may cause actual results to differ from those anticipated by the forward-looking statements, including but not limited to whether Nuvation Bio is successful in commercializing IBTROZI; the challenges associated with conducting drug discovery and initiating or conducting clinical studies due to, among other things, difficulties or delays in the regulatory process, enrolling subjects or manufacturing or acquiring necessary products; the emergence or worsening of adverse events or other undesirable side effects; risks associated with preliminary and interim data, which may not be representative of more mature data; whether Nuvation Bio meets its post-marketing requirements and commitments for IBTROZI; and competitive developments. Risks and uncertainties facing Nuvation Bio are described more fully in its Form 10-K filed with the SEC on March 2, 2026 under the heading “Risk Factors,” and other documents that Nuvation Bio has filed or will file with the SEC. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this press release. Nuvation Bio disclaims any obligation or undertaking to update, supplement or revise any forward-looking statements contained in this press release.

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NUVATION BIO INC. and Subsidiaries
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31,	
	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 164,086	\$ 35,723
Accounts receivable, net of allowance for credit loss of \$nil and nil, respectively	16,076	12,722
Inventory	11,411	—
Prepaid expenses and other current assets	11,536	7,271
Marketable securities	365,125	466,969
Interest receivable on marketable securities	3,285	3,570
Total current assets	571,519	526,255
Property and equipment, net of accumulated depreciation of \$1,184 and \$874, respectively	564	586
Intangible assets, net of accumulated amortization of \$1,856 and \$448, respectively	11,214	4,622
Operating lease right-of-use assets	3,918	2,402
Other non-current assets	7,607	6,761
Total assets	<u>\$ 594,822</u>	<u>\$ 540,626</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 9,479	\$ 6,348
Current operating lease liabilities	1,880	1,663
Contract liabilities, current portion	7,515	11,117
Liability related to revenue interest financing agreement, current portion	9,585	—
Short-term borrowings	5,724	6,283
Warrant liability	2,865	—
Accrued expenses	45,183	32,833
Total current liabilities	82,231	58,244
Warrant liability	—	2,053
Contract liabilities, net of current portion	11,305	15,572
Non-current operating lease liabilities	2,543	969
Non-current liability related to revenue interest financing agreement, net of deferred financing costs of \$4,241 and \$0, respectively	145,819	—
Long-term borrowings, net of deferred financing costs of \$3,042 and \$0, respectively	47,208	—
Total liabilities	<u>289,106</u>	<u>76,838</u>
Stockholders' equity		
Class A and Class B common stock and additional paid in capital, \$0.0001 par value per share; 1,060,000,000 (Class A 1,000,000,000, Class B 60,000,000) shares authorized as of December 31, 2025 and December 31, 2024, 346,503,675 (Class A 345,503,675, Class B 1,000,000) and 337,837,872 (Class A 336,837,872, Class B 1,000,000) shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	1,421,273	1,373,958
Accumulated deficit	(1,115,370)	(910,743)
Accumulated other comprehensive income	(187)	573
Total stockholders' equity	<u>305,716</u>	<u>463,788</u>
Total liabilities and stockholders' equity	<u>\$ 594,822</u>	<u>\$ 540,626</u>

NUVATION BIO INC. and Subsidiaries

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except per share data)

	Three Months Ended December 31,		Years Ended December 31,	
	2025	2024	2025	2024
Revenues:				
Product revenue, net	\$ 15,702	\$ —	\$ 24,663	\$ —
Collaboration and license agreements revenue	26,163	5,711	38,239	7,873
Total revenues	41,865	5,711	62,902	7,873
Costs and expenses:				
Cost of sales	349	—	856	—
Cost of collaboration and license agreements revenue	930	4,216	8,442	7,078
Research and development	34,297	29,299	115,106	99,119
Acquired in-process research and development	—	—	—	425,070
Selling, general and administrative	40,326	26,138	151,562	69,233
Total costs and expenses	75,902	59,653	275,966	600,500
Loss from operations	(34,037)	(53,942)	(213,064)	(592,627)
Other income (expense):				
Interest income	5,296	6,062	21,430	27,062
Interest expense	(6,673)	(89)	(13,682)	(341)
Investment advisory fees	(166)	(227)	(722)	(976)
Change in fair value of warrant liability	(1,127)	(1,145)	(812)	(936)
Realized gain (loss) on marketable securities	3	(12)	5	(12)
Net loss on disposal of fixed assets	(3)	—	(33)	—
Other income (expense)	115	(92)	2,251	(109)
Total other income (expense), net	(2,555)	4,497	8,437	24,688
Loss before income taxes	(36,592)	(49,445)	(204,627)	(567,939)
Provision for income taxes	—	—	—	—
Net loss	\$ (36,592)	\$ (49,445)	\$ (204,627)	\$ (567,939)
Net loss attributable to common stockholders				
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.11)	\$ (0.15)	\$ (0.60)	\$ (2.11)
Weighted average common shares outstanding, basic and diluted	344,339	336,934	341,541	268,772
Comprehensive loss:				
Net loss	\$ (36,592)	\$ (49,445)	\$ (204,627)	\$ (567,939)
Other comprehensive loss, net of taxes:				
Currency translation adjustment	(1,006)	1,131	(1,501)	537
Change in unrealized gain (loss) on available-for-sale securities	958	(1,939)	741	(145)
Comprehensive loss	\$ (36,640)	\$ (50,253)	\$ (205,387)	\$ (567,547)