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: January 31, 2025
(Date of earliest event reported)

ANAPTYSBIO, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-37985**	**20-3828755**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

10770 Wateridge Circle, Suite 210,
San Diego, CA 92121
(Address of Principal Executive Offices, and Zip Code)

(858) 362-6295
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former name or former address, if changed since last report.)

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

☐Written communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐Pre-commencement communication 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 $0.001 per share	ANAB	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 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §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 1.01 Entry into a Material Definitive Agreement.

On January 31, 2025, AnaptysBio, Inc. (**"*Anaptys*"**) entered into an Exclusive License Agreement (the **"*License Agreement*"**) with Vanda Pharmaceuticals Inc. (**"*Vanda*"**) pursuant to which Anaptys granted to Vanda an exclusive, global license for the development and commercialization of imsidolimab (IL-36R antagonist mAb), which has completed two registration-enabling global Phase 3 trials, GEMINI-1 and GEMINI-2, evaluating the safety and efficacy of imsidolimab in patients with Generalized Pustular Psoriasis (GPP).

Pursuant to the terms of the License Agreement, Anaptys will receive an upfront payment of $10 million and a $5 million payment for existing drug supply. Anaptys is also eligible to receive up to $35 million for future regulatory approval and sales milestones in addition to a 10% royalty on net sales.

The License Agreement includes various representations, warranties, covenants, indemnities, and other customary provisions and contains customary provisions for termination (i) by Vanda following the three-year anniversary of the effective date of the License Agreement upon at least 12 months' prior written notice to Anaptys or (ii) by either party in the event of breach of the License Agreement (subject to cure), subject, in each case, to certain reversion rights, or upon the other party's bankruptcy.

The foregoing summary of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the License Agreement. A copy of the License Agreement will be filed as an exhibit to AnaptysBio's Quarterly Report on Form 10-Q for the quarter ended March 31, 2025.

Item 7.01. Regulation FD.

On February 3, 2025, AnaptysBio issued a press release announcing the entry into the License Agreement with Vanda, a copy of which is attached hereto as Exhibit 99.1.

The information in this Item 7.01, including Exhibit 99.1, shall not be deemed "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 incorporated by reference into any other filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Exhibit Number	Exhibit Title or Description
99.1	Press release issued by AnaptysBio, Inc. regarding the Vanda Exclusive License Agreement, dated January 31, 2025.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document).

SIGNATURES

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

AnaptysBio, Inc.

Date: February 3, 2025

By: /s/ Eric Loumeau

Name: Eric Loumeau

Title: Chief Legal Officer

Vanda Pharmaceuticals and Anaptys Announce
Exclusive Global License Agreement
for Vanda to Develop and Commercialize Imsidolimab, an IL-36R Antagonist

- Imsidolimab has successfully completed two global Phase 3 studies in Generalized Pustular Psoriasis
- Vanda expects to immediately begin preparing BLA and MAA applications for the US and EU
- Anaptys to receive $15 million from Vanda, comprised of a $10 million upfront payment and $5 million for existing drug supply
- Anaptys to receive a 10% royalty on global net sales of imsidolimab

WASHINGTON AND SAN DIEGO, Feb. 3, 2025 —Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) and AnaptysBio, Inc. (Anaptys) (Nasdaq: ANAB) today announced an exclusive, global license agreement for the development and commercialization of imsidolimab (IL-36R antagonist mAb), which has successfully completed two registration-enabling global Phase 3 trials, GEMINI-1 and GEMINI-2, evaluating the safety and efficacy of imsidolimab in patients with Generalized Pustular Psoriasis (GPP).

GPP is a rare skin disorder often caused by mutations in the IL36RN gene that codes for a regulatory protein that balances the activity of the proinflammatory IL-36 family of cytokines. Dysregulation of this balance in IL-36 signaling leads to severe chronic skin inflammation with pustules and systemic symptoms which carry significant morbidity and mortality often associated with sepsis and multi-organ failure.[1]

Imsidolimab inhibits the function of the IL-36R, compensating for the deficiency of the endogenous IL-36 regulator in patients with GPP. Imsidolimab has successfully concluded its development program in GPP, including the GEMINI-1 and GEMINI-2 global Phase 3 studies.

In 2025, Vanda intends to initiate and complete the technology transfer activities and will immediately begin preparing the BLA and MAA applications for the US and EU and making preparations for commercialization.

“We are excited to add imsidolimab to Vanda’s product portfolio for rare orphan disorders, as well as explore the potential of this IL-36 signal regulator in the treatment of additional inflammatory conditions where the IL-36 homeostatic balance is dysregulated,” said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board. “Imsidolimab has great synergy with our commercial portfolio, leveraging both our rare disease expertise in the US and EU as well as the anti-inflammatory portfolio that includes Ponvory® for multiple sclerosis, psoriasis and ulcerative colitis.”

GPP prevalence estimates in the general population vary considerably, between 1.76 and 124 patients per million persons worldwide.[2] The majority of GPP cases are caused by genetic variants in IL36RN.[3,4] Loss-of-function mutations in IL36RN are mostly missense mutations in a recessive pattern and result in unrestricted IL-36 activity.[5,6]

"GPP is a severely debilitating, life-threatening skin disease in need of novel therapeutic approaches," said Johann Gudjonsson, M.D., Ph.D., Arthur C. Curtis Professor of Molecular Skin Immunology and Scholar of the Taubman Medical Research Institute, University of Michigan. "The positive Phase 3 data, demonstrating GPP patients achieved rapid disease clearance through Week 4 after a single dose of infused imsidolimab, and maintained clear to almost clear skin for at least 24 weeks, with no clinically meaningful safety signals, represents a promising new option for patients living with this disease. I'm excited imsidolimab is progressing toward a regulatory filing this year."

"Vanda is an ideal partner for imsidolimab due to their strong regulatory and commercial capabilities in the US and Europe, evidenced by successful recent launches in specialty and rare diseases, and their commitment to invest in label expansion across their therapeutic portfolio, including their growing presence in inflammatory disease," said Daniel Faga, president and chief executive officer of Anaptys. "Following our productive pre-BLA meeting with FDA in 2024, we look forward to Vanda's BLA and MAA submissions later in 2025, with the hope that this potentially differentiated therapeutic option will be made available for patients living with GPP, a burdensome, and sometimes life-threatening skin disease."

Under the terms of the agreement, Vanda will make to Anaptys an upfront payment of $10 million and a $5 million payment for existing drug supply. Anaptys is also eligible to receive up to $35 million for future regulatory approval and sales milestones in addition to a 10% royalty on net sales. Vanda will receive an exclusive global license to develop, manufacture and commercialize imsidolimab.

Guggenheim Securities acted as financial advisor and Fenwick & West LLP served as legal counsel to Anaptys on this transaction. Cantor Fitzgerald & Co. acted as financial advisor and Orrick, Herrington & Sutcliffe LLP served as legal counsel to Vanda.

About GEMINI-1 and GEMINI-2 Studies

In the 45-patient GEMINI-1 Phase 3 trial, patients were randomized 1:1:1 to receive a single infusion of 750mg intravenous (IV) imsidolimab, 300mg IV imsidolimab or placebo at Day 0. Of the patients who received a single dose of 750mg IV imsidolimab, 53% achieved a GPP Physician Global Assessment (GPPPGA) score of 0/1 (clear or almost clear skin) at Week 4 (primary endpoint), compared to 13% of the patients on placebo (p=0.0131). Of the patients who received a single dose of 300mg IV imsidolimab, 53% achieved GPPPGA 0/1 at Week 4.

Sixteen GPPPGA 0/1 responder patients from GEMINI-1 were subsequently re-randomized to monthly maintenance dosing of either 200mg subcutaneous (SC) imsidolimab or placebo in the GEMINI-2 Phase 3 trial. Patients were followed for at least 24 weeks and up to a maximum of 92 weeks. Of the eight responding patients from GEMINI-1 who were re-randomized to monthly 200mg SC imsidolimab maintenance therapy, 100% maintained a GPPPGA score of 0/1 and none of them experienced a flare. Of the remaining eight responding patients from GEMINI-1 who were re-randomized to placebo, 25% maintained a GPPPGA score of 0/1 and 63% experienced a flare.

Data from both trials demonstrated a consistent, favorable safety and tolerability profile with no treatment-related serious adverse events (SAEs) or SAEs leading to discontinuation reported in imsidolimab-treated patients.

About Imsidolimab and GPP

Imsidolimab is a fully humanized IgG4 antibody that inhibits the function of the interleukin-36-receptor, or IL-36R, that is being developed for the treatment of GPP. Regulatory and patent exclusivity is expected to extend into the late 2030s.

GPP is a rare, chronic, systemic autoinflammatory disease that is potentially life-threatening, if left untreated.

During a GPP flare, individuals experience the sudden eruption of painful pustules. These pustules appear over large areas of the skin, accompanied by redness, severe itchiness, and dry, cracked, or scaly skin. People with GPP may also experience more general symptoms such as fever, headache, extreme tiredness, or a burning sensation on the skin.

About Vanda Pharmaceuticals, Inc.

Vanda is a leading global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals Inc., please visit www.vandapharma.com and follow us on X @vandapharma.

About Anaptys

Anaptys is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics for autoimmune and inflammatory diseases. Its lead program, rosnilimab, a depleter and agonist targeting PD-1+ T cells, is in a Phase 2b trial for the treatment of rheumatoid arthritis and in a Phase 2 trial for the treatment of ulcerative colitis. Other antibodies in its portfolio include ANB033, an anti-CD122 antagonist, in a Phase 1 trial and ANB101, a BDCA2 modulator, soon to enter clinical development. Anaptys has also discovered multiple therapeutic antibodies licensed to GSK in a financial collaboration for immuno-oncology, including an anti-PD-1 antagonist (Jemperli (dostarlimab-gxly)) and an anti-TIM-3 antagonist (cobolimab, GSK4069889). To learn more, visit www.AnaptysBio.com or follow us on LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: the anticipated timing of the preparation and submission of regulatory filings in the US and EU and the initiation and completion of technology transfer activities; Vanda’s plans with respect to its commercial launch activities; the estimated prevalence of GPP; the commercial availability of imsidolimab to treat patients with GPP; the potential for Anaptys to receive any royalties or milestone payments from the Vanda license agreement; and the potential for any patent life extension for imsidolimab. Statements including words such as “plan,” “intend,” “continue,” “expect,” or “ongoing” and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements are subject to risks and uncertainties that may cause each company’s actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to each company’s ability to advance its product candidates, obtain regulatory approval of and ultimately commercialize each of its product candidates, the timing and results of preclinical and clinical trials, each company’s ability to fund development activities

and achieve development goals, each company's ability to protect intellectual property, and the accuracy of the of the estimates of the number of patients with GPP worldwide, and other risks and uncertainties described under the heading "Risk Factors" in documents each of the companies files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and each of the companies undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

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