



DIVE BRIEF

Adlai Nortye IPO gives old Novartis cancer drug new life

The proceeds will fund a Phase 3 test of a medicine once known as buparlisib and tested by Novartis in dozens of trials.

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Dive Brief:

- Cancer drug developer Adlai Nortye on Thursday raised \$57.5 million in an initial public offering, becoming the 16th biotechnology company to debut on a U.S. stock exchange this year, according to BioPharma Dive data.
- The company sold 2.5 million shares at \$23 apiece — a smaller offering than it had pitched in early August. Nippon Kayaku, a licensing partner and Japan-based pharmaceutical manufacturer, also agreed to acquire \$40 million in additional shares in a concurrent private financing deal, according to a regulatory filing.
- The offering will fund the development of a targeted cancer drug once owned by Novartis. That medicine, formerly known as buparlisib and now AN2025, is in late-stage trials for a form of head and neck cancer and in earlier testing against other solid tumors.

Dive Insight:

Near the end of the last decade, Novartis had two similar drugs advancing through clinical development. Known as PI3 kinase inhibitors because of the enzyme they target, the drugs steadily moved through human testing.

One, Piqray, has since reached market, winning regulatory approval in 2019 for certain breast cancer patients. It's been modestly successful, generating \$373 million in worldwide sales last year.

In 2018, Novartis offloaded the other, buparlisib, to Adlai Nortye, then a privately held China-based startup. Novartis did so despite having studied buparlisib in dozens of trials and over 4,200 patients. Among them was a Phase 3 study in a common form of breast cancer that met its main goal, but revealed safety issues that "[did] not support its further development" in that setting, wrote investigators in a paper published in *Lancet Oncology* in December 2017.

Novartis licensed buparlisib to Adlai Nortye for only \$9.5 million upfront in a heavily backloaded deal, according to the biotech's IPO filing. Novartis still stands to receive additional milestone payments and, if the drug is approved, sales royalties.

Adlai Nortye has focused on buparlisib's potential in different settings and in combination with other drugs. The furthest along is a late-stage study testing the drug and chemotherapy in people whose head and neck cancers have progressed after a commonly used immunotherapy.

The company, which operates in China and the U.S. through subsidiaries owned by a Cayman Islands holding company, will report findings next year. It claims it could file for an accelerated approval afterwards if results are positive.

The biotech is also evaluating buparlisib's use in solid tumors with so-called PIK3CA mutations, the group for which Piqray is approved for use in breast cancer.

The Food and Drug Administration has recently stepped up scrutiny of PI3K inhibitors due to safety concerns that emerged during testing in certain blood cancers. A panel of experts earlier this year voted to raise the approval standards for the medicines, at least when considering broader use in lymphomas and leukemias.

Adlai Nortye's stock offering, which the company initially set plans for in late July, follows positive signs for what has otherwise been a moribund IPO market this year. Earlier this month, RayzeBio and Neumora Therapeutics successfully pulled off lucrative IPOs amid a flurry of activity that also saw chip designer ARM and the grocery delivery company Instacart price offerings.