

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

Filing Date: **2013-01-15** | Period of Report: **2013-01-15**
SEC Accession No. [0001079973-13-000032](#)

([HTML Version](#) on [secdatabase.com](#))

FILER

Venaxis, Inc.

CIK: **1167419** | IRS No.: **841553387** | State of Incorporation: **CO** | Fiscal Year End: **1231**
Type: **8-K** | Act: **34** | File No.: **001-33675** | Film No.: **13529206**
SIC: **2835** In vitro & in vivo diagnostic substances

Mailing Address
1585 S. PERRY STREET
CASTLE ROCK CO 80104

Business Address
1585 S. PERRY STREET
CASTLE ROCK CO 80104
(303) 794-2000

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

CURRENT REPORT

**PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported) January 15, 2013

Venaxis, Inc.

(Exact name of Registrant as specified in its charter)

Colorado

**(State or other jurisdiction of
incorporation or organization)**

001-33675

(Commission File Number)

84-1553387

(I.R.S. Employer Identification No.)

**1585 South Perry Street
Castle Rock, Colorado**

(Address of principal executive offices)

80104

(Zip Code)

Registrant's telephone number, including area code:

(303) 794-2000

(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 communications 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 communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))**
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))**

Item 8.01. Other Events.

On January 15, 2013, Venaxis, Inc., (the “Company”) issued a press release titled — “Venaxis Initiates Patient Enrollment for APPY1 Pivotal Study.” The press release is filed as Exhibit 99.1 to this Form 8-K.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibits

99.1 Press Release of Venaxis, Inc. titled “Venaxis Initiates Patient Enrollment for APPY1 Pivotal Study,” issued January 15, 2013.

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.

Venaxis, Inc.
(Registrant)

January 15, 2013

By: /s/ Jeffrey G. McGonegal

Name: Jeffrey G. McGonegal

Title: Chief Financial Officer

Venaxis Initiates Patient Enrollment for APPY1 Pivotal Study

CASTLE ROCK, Colo., January 15, 2013 — Venaxis, Inc. (Nasdaq: APPY), an *in vitro* diagnostic company focused on obtaining FDA clearance and commercializing its blood-based appendicitis test, APPY1, today announced that it has begun enrolling patients into its pivotal clinical study in the United States. Based on current enrollment expectations, the Company anticipates completing the study in six to eight months and filing with the FDA for regulatory clearance of APPY1 in the fourth quarter 2013.

Steve Lundy, President and CEO of Venaxis, stated, “With our pivotal study now underway, we anticipate 2013 will be a transformative year for Venaxis. The pivotal clinical study is being conducted at 28 leading hospital sites, each of which are enthusiastic to assist us in completing the study as expeditiously as possible. We believe our overall success will be driven by continued execution on clinical and regulatory milestones, and we are pleased to commence patient enrollment in our pivotal U.S. study just days after announcing that APPY1 is now a CE Marked product in Europe. Over the coming months while the study is ongoing, we intend to launch APPY1 in initial EU territories, as well as continue working across our network of more than 100 U.S. hospitals in order to develop the market for APPY1.”

About Venaxis, Inc.

Venaxis, Inc. is an *in vitro* diagnostic company focused on the clinical development and commercialization of its blood-based appendicitis test, APPY1. The unique appendicitis test has projected high sensitivity and negative predictive value and is designed to aid in the identification of patients at low risk for acute appendicitis, allowing for more conservative patient management. APPY1 is being developed initially for pediatric, adolescent and young adult patients with abdominal pain, as this population is at the highest risk for appendicitis and has the highest risk of long-term health effects associated with CT imaging. For more information, visit www.venaxis.com.

Forward-Looking Statements

This press release includes "forward-looking statements" of Venaxis, Inc. ("Venaxis") (formerly AspenBio Pharma, Inc.) as defined by the Securities and Exchange Commission ("SEC"). All statements, other than statements of historical fact, included in this press release that address activities, events or developments that Venaxis believes or anticipates will or may occur in the future are forward-looking statements. These statements are based on certain assumptions made based on experience, expected future developments and other factors Venaxis believes are appropriate in the circumstances. Such statements are subject to a number of assumptions, risks and uncertainties, many of which are beyond the control of Venaxis. Investors are cautioned that any such statements are not guarantees of future performance. Actual results or developments may differ materially from those projected in the forward-looking statements as a result of many factors, including our ability to successfully complete required product development and modifications in a timely and cost effective manner, complete clinical trial activities for APPY1 required for FDA submission, obtain FDA clearance or approval, complete and maintain CE Marking, cost effectively manufacture and generate revenues from APPY1, execute agreements required to successfully advance the company's objectives, retain the management team to advance the products, overcome adverse changes in market conditions and the regulatory environment, obtain and enforce intellectual property rights, and realize value of intangible assets. Furthermore, Venaxis does not intend (and is not obligated) to update publicly any forward-looking statements. The contents of this press release should be considered in conjunction with the risk factors contained in Venaxis' recent filings with the SEC, including its Form 10-Q for the period ended September 30, 2012, filed on November 7, 2012.

For Investors & Media:

Joshua Drumm, PhD / Jason Rando
Tiberend Strategic Advisors, Inc.
(212) 827-0020
jdrumm@tiberend.com
jrando@tiberend.com