ADVENTRX PHARMACEUTICALS INC
Form S-1/A
September 03, 2009

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As filed with the Securities and Exchange Commission on September 3, 2009
Registration No. 333-160778

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 1
to
Form S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ADVENTRX Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**84-1318182**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification Number)*

6725 Mesa Ridge Road,
Suite 100,
San Diego, CA 92121
(858) 552-0866
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Brian M. Culley
Principal Executive Officer
ADVENTRX Pharmaceuticals, Inc.

6725 Mesa Ridge Road, Suite 100
San Diego, CA 92121
Telephone: (858) 552-0866
(Name, address, including zip code, and telephone number, including area code, of agent for service)

With a Copy to:

Michael S. Kagnoff, Esq. **DLA Piper LLP (US)** **4365 Executive Drive, Suite 1100** **San Diego, CA 92121** **Telephone: (858) 677-1400** **Facsimile: (858) 677-1401**	**Patrick L. Keran, Esq.** **Principal Financial and Accounting Officer and General Counsel** **ADVENTRX Pharmaceuticals, Inc.** **6725 Mesa Ridge Road, Suite 100** **San Diego, CA 92121** **Telephone: (858) 552-0866**	**Harvey J. Kesner, Esq.** **Sichenzia Ross Friedman Ference LLP** **61 Broadway, Suite 3200** **New York, NY 10006** **Telephone: (212) 930-9700** **Facsimile: (212) 930-9725**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective statement for the same offering o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company þ

CALCULATION OF REGISTRATION FEE

			Amount of

Title of Each Class of Securities to be Registered(1)	Proposed Maximum Aggregate Offering Price(2)	Registration Fee(3)
Common Stock, par value $0.001 per share	$ 17,250,000	$ 963

(1) Includes 330,882 shares subject to the underwriters over-allotment option.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act. Pursuant to Rule 416 under the Securities Act of 1933, as amended (the Securities Act), the shares being registered hereunder include such indeterminate number of shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends, anti-dilution provisions, or similar transactions. No additional registration fee is being paid for these shares.

(3) Of this amount, $558 previously paid.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS SUBJECT TO COMPLETION September 3, 2009

2,205,882 Shares

Common stock

This is a firm commitment public offering of $15,000,000 of common stock or 2,205,882 shares (based on an assumed public offering price of $6.80 per share).

Our common stock is listed on the NYSE Amex under the symbol ANX. We have applied for the listing of our common stock on The NASDAQ Capital Market under the symbol ADVX. Prior to the effective date of the registration statement of which this prospectus is a part, we will effect a reverse stock split of our outstanding common stock on a 40-for-1 basis. On August 28, 2009, the last reported sale price of our common stock on the NYSE Amex was $6.80 per share (giving effect to the 40-for-1 reverse stock split).

Investing in our common stock involves a high degree of risk. Before buying any shares, you should read the discussion of material risks of investing in our common stock in Risk Factors beginning on page 6.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per share	Total
Public offering price	$	$
Underwriting discounts and commissions[1]	$	$
Proceeds, before expenses, to us[2]	$	$

(1) Does not include a non-accountable expense allowance equal to 1% of the gross proceeds of this offering payable to Rodman & Renshaw, LLC, the representative of the underwriters.

(2) We estimate the total expenses of this offering, excluding the underwriting discounts and commissions and non-accountable expense allowance, will be approximately $325,000.

The underwriters may also purchase up to an additional 330,882 shares of our common stock at the public offering price, less the underwriting discounts and commissions, to cover over-allotments, if any, within 45 days of the date of this prospectus.

The underwriters are offering our common stock as set forth under Underwriting. Delivery of the shares will be made on or about , 2009.

Rodman & Renshaw, LLC
Sole Book-Running Manager

Caris & Company

You should rely only on the information contained in this prospectus and any free writing prospectus prepared by us or on our behalf. We have not authorized anyone to provide you with different or additional information. If anyone provides you with different or additional information, you should not rely on it. We are not making offers to sell, or seeking offers to buy, these securities in any state or other jurisdiction where the offers and sales are not permitted. The information contained in this prospectus is accurate only as of the date hereof, regardless of the time of delivery of this prospectus or of any sale of the securities offered hereby. Our business, financial condition, results of operations and prospects may have changed since the date of this prospectus.

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Our trademark CoFactor® is registered in the United States Patent and Trademark Office (in the Supplemental Register) under Registration No. 2,946,934, for use in connection with chemotherapy modulators derived from folic acid. We are developing commercial names for our other product candidates. All other trademarks, service marks or trade names appearing in this prospectus, including but not limited to Navelbine® and Taxotere®, are the property of their respective owners. Use or display by us of other parties trademarks, service marks, trade names, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark, service mark, trade name, trade dress or product owners. As indicated in this prospectus, we have included market data and industry forecasts that were obtained from industry publications.

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PROSPECTUS SUMMARY

This summary highlights selected information about us and this offering contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements contained elsewhere in this prospectus. It may not contain all of the information that is important to you. You should carefully read this entire prospectus, including the risks and uncertainties discussed under the heading Risk Factors below, our consolidated financial statements and the notes related thereto, our condensed consolidated financial statements and the notes related thereto, and the other documents included in or to which this prospectus refers, before making an investment decision. When used in this prospectus, the terms ADVENTRX, we, our, us and the Company refer to ADVENTR Pharmaceuticals, Inc. and its subsidiaries, unless otherwise indicated or the context otherwise requires.

About ADVENTRX Pharmaceuticals, Inc.

We are a development-stage specialty pharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates for the treatment of cancer. We seek to improve the performance of existing drugs by addressing limitations associated principally with their safety and use. We have not yet marketed or sold any products or generated any significant revenue.

Our lead product candidates, ANX-530 (vinorelbine emulsion) and ANX-514 (docetaxel emulsion), are novel emulsion formulations of currently marketed chemotherapy drugs. We believe ANX-530 and ANX-514 may improve the safety of the currently marketed reference products, Navelbine (vinorelbine tartrate) and Taxotere (docetaxel), respectively, by:

- Reducing the incidence and severity of adverse effects; and
- Improving their pharmacoeconomics and convenience to healthcare practitioners and patients.

Following the registered direct equity financing that we completed in June 2009, we re-started certain development activities that we had suspended in March 2009 to conserve cash while we evaluated strategic options, pursued financing alternatives and considered other alternatives. Specifically, we re-started the final manufacturing activities related to submitting a New Drug Application, or NDA, for ANX-530 to seek approval of the United States Food and Drug Administration, or FDA, to market ANX-530 in the United States.

In August 2009, we announced that, while we continue to evaluate our ANX-530 bioequivalence and preclinical data, we plan to submit an NDA for ANX-530 before the end of 2009. Assuming we submit an ANX-530 NDA in December 2009, and the FDA does not request and we do not otherwise provide additional information or clarification with respect to our submission, we expect a response from the FDA to our submission in the fourth quarter of 2010.

In addition, we continue to evaluate the data from our recently-completed bioequivalence study of ANX-514 and we plan to seek a meeting with the FDA to discuss the results.

Our Strategy

Our goal is to be a leading specialty pharmaceutical company focused on developing and commercializing proprietary product candidates that improve the performance of currently approved products. Our near-term strategy is to obtain marketing approval of our lead product candidates and either partner with leading organizations or establish an infrastructure to support marketing, distributing and selling these products in the U.S. and abroad, should they be

approved. Longer term, we intend to acquire additional product candidates that fit our areas of expertise. Specifically, we intend to:

Seek marketing approval for ANX-530 and ANX-514 in the U.S. We are applying our operational experience to complete and seek approval of NDAs for ANX-530 and ANX-514 that we intend to submit to the FDA. In August 2009, we announced that, while we continue to evaluate the bioequivalence and preclinical data, we plan to submit an NDA for ANX-530 before the end of 2009. In addition, we are continuing to evaluate the data from our recently-completed bioequivalence study of ANX-514 and plan to seek a meeting with the FDA to discuss the results.

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Establish sales and marketing capabilities for ANX-530 and ANX-514 in the U.S. We intend to gain access to a substantial portion of the U.S. markets for ANX-530 and ANX-514 through a small, specialized sales force targeting distributors, provider networks and group purchasing organizations. For the near-term, we intend to maintain our current cost-efficient and flexible infrastructure by limiting the number of our full-time employees, engaging consultants on a project basis and outsourcing substantially all of our development activities to specialized vendors and contract development organizations. As we near regulatory approval of our product candidates, we plan to establish the infrastructure and relationships necessary to access what we believe will be concentrated markets for ANX-530 and ANX-514. However, we also remain receptive to partnering these product candidates in the U.S. if presented with terms that are sufficiently attractive.

Partner with leading organizations to develop and market ANX-530 and ANX-514 outside the U.S. or globally. We plan to draw on the development, regulatory and commercial expertise of other companies in instances where we believe our product candidates would benefit from such expertise. For markets in which a large sales force is required to gain access, and for markets outside the U.S. and possibly within the U.S., we plan to commercialize products for which we obtain regulatory approval through a variety of licensing, collaboration and distribution arrangements with other pharmaceutical and biotechnology companies. In March 2009, we entered into a license agreement with Shin Poong Pharmaceutical Co., Ltd. pursuant to which we granted Shin Poong an exclusive license to make use and sell ANX-514 in South Korea.

Pursue additional indications and commercial opportunities for ANX-530 and ANX-514 independently and through collaborations. We may increase the value of our product candidates by seeking approval for label changes and pursuing other commercial opportunities. For example, we or a future partner may conduct clinical and non-clinical studies that seek to differentiate ANX-530 and ANX-514 from Navelbine and Taxotere, respectively.

Acquire and develop new and improved formulations of currently marketed products. We may pursue other currently approved products that we believe can be improved, the U.S. markets for which are concentrated and to which we can apply our operational experience.

Net Loss and Recent Financing Activity

We have devoted substantially all of our resources to research and development activities or to acquisition of our product candidates and have experienced annual net losses since inception, accumulating net losses totaling approximately $144.3 million as of June 30, 2009, and we expect to incur substantial losses for the foreseeable future. As of June 30, 2009, we had approximately $5.4 million in cash and cash equivalents and $2.2 million in working capital, which working capital amount reflects a liability of $1.4 million that was eliminated on July 6, 2009 following the closing of a registered direct equity financing that we completed on July 6, 2009. We do not expect to generate positive net cash flows for the foreseeable future. Historically, we have funded our operations primarily through sales of our equity securities. Our independent auditor s report for the year ended December 31, 2008 includes an explanatory paragraph stating that our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

On June 12, 2009, July 6, 2009 and August 10, 2009, we completed registered direct equity financings involving, respectively, shares of our 0% Series A Convertible Preferred Stock, 5% Series B Convertible Preferred Stock and 5% Series C Convertible Preferred Stock, which financings resulted in a total of $4.3 million in gross proceeds and $3.7 million in net proceeds, after deducting the fees of our placement agent in those financings and our estimated offering expenses, but before deducting our dividend and related payment obligations. All of these shares of

Convertible Preferred Stock subsequently have been converted into shares of our common stock and, pursuant to the terms of our 5% Series B Convertible Preferred Stock and our 5% Series C Convertible Preferred Stock, we paid an aggregate of $455,500 to the holders of such Convertible Preferred Stock in connection with such conversions. We may receive up to $1.2 million of additional proceeds from the exercise of warrants issued in our June 2009 financing; however, those warrants are not exercisable until December 13, 2009 and their exercise is subject to certain ownership limitations.

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Reverse Stock Split

At a special meeting of our stockholders on August 25, 2009 called by our board of directors, our stockholders approved authorizing our board of directors to effect a reverse stock split of our outstanding common stock at a ratio in the discretion of the board of directors that is not less than 2-for-1 or greater than 50-for-1. Prior to the closing of the offering described in this prospectus, we will effect a reverse stock split of our outstanding common stock on a 40-for-1 basis. This stock split will not affect the authorized number of shares of our capital stock.

Risk Factors

We face numerous risks and uncertainties that could materially and adversely affect our business, results of operations and financial condition, including the risk that we may not be able to raise sufficient capital to continue our business operations, which could result in our inability to continue as a going concern, and the risk that we may be unable to regain compliance with the continued listing requirements of the NYSE Amex, the securities exchange on which our common stock is listed, and our common stock may be delisted from that exchange. For additional discussion of the risk and uncertainties we face, see Risk Factors below.

Corporate Information

Our business was incorporated in Delaware in December 1995. In October 2000, we merged our wholly-owned subsidiary, Biokeys Acquisition Corp., with and into Biokeys, Inc. and changed our name to Biokeys Pharmaceuticals, Inc. In May 2003, we merged Biokeys, Inc., our wholly-owned subsidiary, with and into us and changed our name to ADVENTRX Pharmaceuticals, Inc. In July 2004, we formed a wholly-owned subsidiary, ADVENTRX (Europe) Ltd., in the United Kingdom primarily to facilitate conducting clinical trials in the European Union and to obtain favorable pricing for discussions with the European Medicines Agency. In April 2006, we acquired SD Pharmaceuticals, Inc. as a wholly-owned subsidiary.

Our executive offices are located at 6725 Mesa Ridge Road, Suite 100, San Diego, California 92121, and our telephone number is (858) 552-0866. Our corporate website is located at www.adventrx.com. Information on our website does not constitute part of this prospectus.

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The Offering

Common stock offered:	2,205,882 shares
Common stock to be outstanding after this offering:	5,328,014 shares
Use of proceeds:	We currently intend to use the net proceeds from this offering to fund activities necessary to advance ANX-530 toward commercialization in the U.S. and to continue development of ANX-514, and for general corporate purposes. Please see Use of Proceeds below.
NYSE Amex symbol:	ANX
Proposed NASDAQ Capital Market symbol:	ADVX
Risk factors:	Investing in our securities involves a high degree of risk and purchasers of our common stock may lose their entire investment. See Risk Factors below and the other information included elsewhere in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.

The number of shares of our common stock to be outstanding immediately after this offering is based on 3,122,132 shares of our common stock outstanding as of August 28, 2009. This number does not include, as of August 28, 2009:

- 148,135 shares of common stock issuable upon the exercise of outstanding stock options issued under our equity incentive plans prior to this offering, at a weighted average exercise price of $32.40 per share;
- 265,431 shares of common stock available for future issuance under our 2008 Omnibus Incentive Plan;
- 516,468 shares of common stock issuable upon the exercise of outstanding warrants issued prior to this offering, at a weighted average exercise price of $50.40 per share; and
- 110,294 shares of common stock issuable upon exercise of warrants to be issued to the representative of the underwriters in connection with this offering, which are not covered by this prospectus, at an exercise price of $ per share (125% of the price of the shares sold in this offering).

Except as otherwise indicated, all information in this prospectus (other than the information contained in our consolidated financial statements and related notes beginning on page F-2 and our unaudited condensed consolidated financial statements and related notes beginning on page F-15) assumes:

- no exercise by the underwriters of their option to purchase up to an additional 330,882 shares of common stock to cover over-allotments;
- a 40-for-1 reverse stock split of our outstanding common stock, which we will effect prior to the effective date of the registration statement of which this prospectus is a part; and

a public offering price of $6.80 per share.

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Summary Financial Data

The following tables set forth our summary statement of operations data for the fiscal years ended December 31, 2008 and 2007, for the three months ended June 30, 2009 and 2008, and our summary balance sheet as of June 30, 2009. Our statement of operations data for the fiscal years ended December 31, 2008 and 2007 were derived from our audited consolidated financial statements included elsewhere in this prospectus. Our statement of operations data for the three months ended June 30, 2009 and 2008 and our balance sheet data as of June 30, 2009 were derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. In the opinion of management the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary for a fair presentation of our operating results and financial position for those periods and as of such dates. The results for any interim period are not necessarily indicative of the results that may be expected for a full year.

The results indicated below and elsewhere in this prospectus are not necessarily indicative of our future performance. You should read this information together with Capitalization, Management s Discussion and Analysis of Financial Condition and Results of Operations, our consolidated financial statements and related notes and our unaudited condensed consolidated financial statements and related notes included elsewhere in this prospectus.

Statement of Operations Data

	Year Ended December 31, 2007	Year Ended December 31, 2008	Three Months Ended June 30, 2008	Three Months Ended June 30, 2009
Revenue	$ 500,000	$ 500,000	$ 500,000	$
Operating Expenses:				
Research and development	15,934,409	17,922,183	4,511,395	1,454,896
Selling, general and administrative	8,678,853	9,719,613	2,635,688	1,071,754
Depreciation and amortization	197,783	168,039	44,116	25,835
Total operating expenses	24,811,045	27,809,835	7,191,199	2,552,485
Loss from operations	(24,311,045)	(27,309,835)	(6,691,199)	(2,552,485)
Interest and other income (expense)	2,169,005	662,342	265,669	(43,056)
Net loss	(22,142,040)	(26,647,493)	(6,425,530)	(2,595,541)
Deemed dividends on preferred stock				(1,232,415)
Net loss applicable to common stock	$ (22,142,040)	$ (26,647,493)	$ (6,425,530)	$ (3,827,956)
Net loss per share basic and diluted	$ (9.85)	$ (11.81)	$ (2.85)	$ (1.11)
Weighted average shares outstanding basic and diluted	2,247,818	2,256,314	2,256,314	2,334,733

Balance Sheet Data

	As of June 30, 2009
Cash and cash equivalents	$ 5,419,227
Total current assets	$ 6,024,057
Total current liabilities	$ 3,870,811
Deficit accumulated during the development stage	$ (132,831,425)
Total stockholders equity	$ 2,295,819

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RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risk factors discussed below, together with all the other information contained in this prospectus before deciding whether to purchase any of our securities. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities, and the occurrence of any of these risks might cause you to lose all or part of your investment.

RISKS RELATED TO OUR BUSINESS

Risks Related to Our Capital Requirements and Operations

We have incurred losses since our inception, we expect our operating expenses to continue to exceed our revenues for the foreseeable future and we may never generate revenues sufficient to achieve profitability.

We are a development stage company and have not generated sustainable revenues from operations or been profitable since inception, and it is possible we will never achieve profitability. We have devoted our resources to developing a new generation of therapeutic products, but such products cannot be marketed until the regulatory process is completed and governmental approvals have been obtained. Accordingly, there is no current source of revenues from operations, much less profits, to sustain our present activities, and no revenues from operations will likely be available until, and unless, our product candidates are approved by the U.S. Food and Drug Administration, or FDA, or other regulatory agencies and successfully marketed, either by us or a partner, an outcome which we are not able to guarantee.

We will need to obtain additional funding to support our planned level of operations, and we may not be able to obtain such capital on a timely basis or on commercially reasonable terms, if at all.

We have experienced significant operating losses in funding the development of our product candidates, accumulating net losses totaling approximately $144.3 million as of June 30, 2009, and we expect to continue to incur substantial operating losses for the foreseeable future, even if we or a future partner of ours is successful in advancing our product candidates to market. As of June 30, 2009, we had approximately $5.4 million in cash and cash equivalents and $2.2 million in working capital, which working capital amount reflects a liability of $1.4 million that was eliminated on July 6, 2009 following the closing of a registered direct equity financing that we completed on July 6, 2009. We do not expect to generate cash flows from sales of our products unless and until our products are approved for marketing, the timing of which we cannot predict accurately. Following the equity financing we completed in June 2009, we re-started the final manufacturing activities related to submitting a New Drug Application, or NDA, for ANX-530 to seek approval of the FDA to market ANX-530 in the United States, or U.S., and intend to continue to evaluate the data from our recently-completed bioequivalence study of ANX-514. We expect to incur substantial costs in connection with activities relating to submitting an NDA for ANX-530 and advancing ANX-530 toward commercialization in the U.S.

Our future expenditures on our programs are subject to many uncertainties, including whether our product candidates will be developed with a partner or independently. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the costs of seeking regulatory approval for our lead product candidates, ANX-530 and ANX-514, including any bioequivalence or clinical studies, process development, scale-up and other manufacturing activities, or

other work required to achieve such approval, as well as the timing of such activities and approval;

the timing and terms of any collaborative, licensing and other strategic arrangements that we may establish;

the cost related to establishing or contracting for sales and marketing capabilities and other commercial capabilities;

the scope, prioritization and number of development and/or commercialization programs we pursue and the rate of progress and costs with respect to such programs;