VICAL INC
Form S-1/A
October 30, 2017
As filed with the Securities and Exchange Commission on October 30, 2017

Registration No. 333-220981

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

VICAL INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	2836 (Primary Standard Industrial Classification Code Number)	93-0948554 (I.R.S. Employer Identification Number)

10390 Pacific Center Court
San Diego, California 92121
(858) 646-1100

(Address, including zip code, and telephone number, including area code, of registrant’s principal executive offices)

Vijay B. Samant
President and Chief Executive Officer
Vical Incorporated
10390 Pacific Center Court
San Diego, California 92121
(858) 646-1100

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Frederick T. Muto, Esq. Sean M. Clayton, Esq. Cooley LLP 4401 Eastgate Mall San Diego, California 92121 (858) 550-6000	Matthew T. Bush, Esq. Latham & Watkins LLP 12670 High Bluff Drive San Diego, California 92130 (858) 523-5400

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, as amended (the “Securities Act”), check the following box.

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.

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.

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 registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
		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 to Section 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price[1]	Amount of registration fee
Common Stock, $0.01 par value per share	$25,070,000	$3,122[2]

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act. Includes the offering price of any additional securities that the underwriter has the option to purchase.

(2) $2,864 was 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 that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act 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.

The information in this preliminary 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 we are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated October 30, 2017

PRELIMINARY PROSPECTUS

VICAL INCORPORATED

10,000,000 Shares of Common Stock

We are offering 10,000,000 shares of our common stock. Our common stock is listed on the NASDAQ Capital Market under the symbol "VICL." On October 27, 2017, the last reported sale price of our common stock on the NASDAQ Capital Market was $2.18 per share. The public offering price per share will be determined between us and the underwriter at the time of pricing, and may be at a discount to the current market price.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions[(1)]	$	$
Proceeds, before expenses, to us	$	$

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(1) In addition, we have agreed to reimburse the underwriter for certain expenses. See "Underwriting" for additional information.

The offering is being underwritten on a firm commitment basis. We have granted the underwriter an option for a period of 30 days from the date of this prospectus to purchase up to an additional 1,500,000 shares of our common stock to cover over-allotments, if any.

Investing in our securities involves a high degree of risk. See the section entitled "Risk Factors" beginning on page 4 of this prospectus and in the documents incorporated by reference into this prospectus for a discussion of risks that should be considered in connection with an investment in our securities.

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.

The underwriter expects to deliver the shares of common stock to purchasers on or about November , 2017.

Sole Book-Running Manager

H.C. Wainwright & Co.

The date of this prospectus is November , 2017

TABLE OF CONTENTS

We have not, and the underwriter has not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriter has not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus or incorporated by reference into this prospectus from our filings with the Securities and Exchange Commission, or SEC, listed in the section of the prospectus entitled "Incorporation of Certain Information by Reference." Because it is only a summary, it does not contain all of the information that you should consider before purchasing our securities in this offering and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere or incorporated by reference into this prospectus. You should read the entire prospectus, the registration statement of which this prospectus is a part, and the information incorporated by reference herein in their entirety, including the "Risk Factors" and our financial statements and the related notes incorporated by reference into this prospectus, before purchasing our securities in this offering. Unless otherwise mentioned or unless the context requires otherwise, all references in this prospectus to "Vical," "we," "our," "us" or similar references mean Vical Incorporated.

Overview

Our Company

We research and develop biopharmaceutical products, including those based on our patented DNA delivery technologies, for the prevention and treatment of serious or life-threatening diseases. We currently have three active product development programs, independent or partnered, in the clinical testing stage in the area of infectious disease comprised of:

- An ongoing Phase 3 trial of ASP0113 for prevention of cytomegalovirus, or CMV, reactivation in hematopoietic stem cell transplant recipients in collaboration with Astellas Pharma Inc., or Astellas. Enrollment of the trial was completed in September 2016 with a total of 515 subjects. Dosing in the trial was completed in April of 2017 and the one-year follow-up period was completed in September 2017. The primary endpoint of the trial is a composite of overall mortality and CMV end organ disease which will be assessed one year after transplantation. Astellas expects top-line data to be available in the first quarter of 2018. We and Astellas continue to make progress towards a Biologics License Application filing in 2018 with the U.S. Food and Drug Administration, or FDA. Astellas has indicated that, if approved, it would seek to commercialize ASP0113 in North America, Europe and Asia.
- An ongoing Phase 2 trial of VCL-HB01, our therapeutic DNA vaccine for reduction of genital herpes lesion recurrences caused by herpes simplex virus type 2, or HSV-2, infection. Recruitment into the Phase 2 trial of VCL-HB01 has been completed with a total of 261 subjects enrolled at 15 U.S. clinical sites. The four-dose vaccination series was completed in July 2017, and all active subjects are currently being monitored for lesion recurrences during a 12-month follow-up period. VCL-HB01 is formulated with Vaxfectin® and encodes two full-length HSV-2 antigens gD and UL46, designed to reduce recurrences in patients with symptomatic genital HSV-2 infection. Healthy adult subjects, 18 to 50 years of age, have been randomized 2:1 to receive either vaccine or placebo to evaluate in a double-blinded fashion the efficacy and safety of the vaccine. The primary endpoint of the study is annualized lesion recurrence rate which is a clinically meaningful endpoint for both patients and treating physicians as it provides important information on the number of recurrences over time in this chronic disease setting. We expect to announce top-line data during the second quarter of 2018.
- A completed first-in-human Phase 1 trial of our novel antifungal VL-2397. The randomized, double-blind, placebo-controlled trial evaluated safety, tolerability and pharmacokinetics of single and multiple ascending doses of intravenous VL-2397 in 96 healthy volunteers. Results point to a favorable safety and pharmacokinetic profile for VL-2397. The full data set was presented as one of four presentations at the ASM Microbe 2017 conference in June. The FDA has advised us that VL 2397 would be eligible for a Limited Use Indication, or LUI, approval assuming a successful outcome of a single Phase 2 trial carried out in accordance with a protocol and statistical analysis plan

consistent with the FDA's advice. The final determination of whether VL-2397 is approvable will be made by the FDA after review of all relevant data. We plan to initiate a Phase 2 trial for the treatment of invasive aspergillosis in acute leukemia patients and allogeneic hematopoietic cell transplant recipients in the fourth quarter of 2017. The FDA has granted us qualified infectious disease product, or QIDP, Orphan Drug and Fast Track designations with respect to VL-2397 for the treatment of invasive aspergillosis.

1

Risks Associated with Our Business and this Offering

An investment in our securities involves a high degree of risk. Prior to making a decision about investing in our securities, you should carefully consider the risks described in the section entitled “Risk Factors” in this prospectus and in the documents incorporated by reference herein, as well as any updates thereto contained in subsequent filings with the SEC or any free writing prospectus. If any of these risks were to occur, our business, financial condition or results of operations would likely suffer. In that event, the value of our securities could decline, and you could lose all or part of your investment. The risks and uncertainties we describe are not the only ones facing us. Additional risks not presently known to us or that we currently deem immaterial may also impair our business, financial condition or results of operations.

Corporate and Other Information

We were incorporated in Delaware in 1987. Our headquarters are located at 10390 Pacific Center Court, San Diego, California 92121. Our telephone number is (858) 646-1100. We maintain an Internet website at www.vical.com. The reference to our Internet address does not constitute incorporation by reference of the information contained on our website.

We are a “smaller reporting company” as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and have elected to take advantage of certain of the scaled disclosure available for smaller reporting companies in this prospectus as well as our filings under the Exchange Act.

Any brand names or trademarks appearing in this prospectus or in documents incorporated by reference in this prospectus are the property of their respective owners.

The Offering

Common stock offered by us in this offering	10,000,000 shares.
Common stock to be outstanding after this offering	21,547,980 shares.
Option to purchase additional shares	The underwriter has a 30-day option to purchase up to an additional 1,500,000 shares of our common stock to cover over-allotments, if any.
Use of proceeds	We intend to use the net proceeds from this offering for general corporate purposes, including clinical trial expenses, research and development expenses, general and administrative expenses, manufacturing expenses, and potential acquisitions of companies and technologies that complement our business. See “Use of Proceeds.”
Risk factors	You should read the “Risk Factors” section of this prospectus for a discussion of certain of the factors to consider carefully before deciding to purchase any shares of our common stock in this offering.
National Securities Exchange Listing	Our common stock is listed on the NASDAQ Capital Market under the symbol “VICL.”

The number of shares of our common stock to be outstanding after this offering is based on 11,547,980 shares of common stock outstanding as of September 30, 2017 and excludes as of that date:

- 1,754,281 shares of common stock issuable upon the exercise of outstanding stock options, at a weighted-average exercise price of $12.06 per share;
- 50,162 shares of common stock issuable upon the settlement of outstanding restricted stock units; and
- 638,959 shares of common stock reserved for future issuance under our Amended and Restated Stock Incentive Plan, or the Incentive Plan.

Such number also excludes 1,058,487 shares of common stock sold under our At-The-Market Issuance Sales Agreement with IFS Securities, Inc. after September 30, 2017.

Unless otherwise indicated, all information contained in this prospectus assumes no exercise by the underwriter of its over-allotment option.

RISK FACTORS

An investment in our securities involves a high degree of risk. Prior to making a decision about investing in our securities, you should carefully consider the risks described below, together with all of the other information included or incorporated by reference in this prospectus, including the risks described in the section entitled “Risk Factors” contained in our most recent quarterly report on Form 10-Q, which has been filed with the SEC and is incorporated by reference in this prospectus, as well as any updates thereto contained in subsequent filings with the SEC or any free writing prospectus. If any of these risks were to occur, our business, financial condition or results of operations would likely suffer. In that event, the value of our securities could decline, and you could lose all or part of your investment. The risks and uncertainties we describe are not the only ones facing us. Additional risks not presently known to us or that we currently deem immaterial may also impair our business, financial condition or results of operations.

Risks Related to this Offering

We will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled “Use of Proceeds,” and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management may not apply the net proceeds from this offering in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

There may be future sales of our securities or other dilution of our equity, which may adversely affect the market price of our common stock.

We are generally not restricted from issuing additional common stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. The market price of our common stock could decline as a result of sales of common stock or securities that are convertible into or exchangeable for, or that represent the right to receive, common stock after this offering or the perception that such sales could occur.

Even if this offering is successful, we will need to raise additional capital in the future to continue operations, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

To date, we have not sold, or received approval to sell, any pharmaceutical products. We do not expect to sell any pharmaceutical products for at least the next several years. Our net losses were approximately $9.0 million, $9.2 million and $16.5 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had incurred cumulative net losses totaling approximately $413.9 million. Moreover, we expect that our net losses will continue and may increase for the foreseeable future. We may not be able to achieve projected results if we generate lower revenues or receive lower investment income than expected, or we incur greater expenses than expected, or all of the above. Currently our revenues are largely dependent on manufacturing and research services performed under our license agreement with Astellas. That revenue may decrease once the ASP0113 trials are

complete or in the event that the development of the ASP0113 program ceases. We may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses, and losses, some of which could be significant.

We estimate that we will receive net proceeds of approximately $20.0 million from the sale of the securities offered by us in this offering, based on the assumed public offering price of $2.18 per share (the last reported sale price of our common stock on the NASDAQ Capital Market on October 27, 2017), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. In the event of a decrease in the net proceeds to us from this offering as a result of a decrease in the assumed public offering price or the

number of shares offered by us, we may need to raise additional capital sooner than we anticipate or may need to scale back or eliminate certain of our development programs.

We may need to raise more money to continue the research and development necessary to bring our products to market and to establish marketing and additional manufacturing capabilities. We may seek additional funds through public and private stock offerings, government contracts and grants, arrangements with corporate collaborators, borrowings under lines of credit or other sources. We currently have on file a shelf registration statement that allows us to raise proceeds from the sale of common stock, preferred stock, debt securities and/or warrants subject to applicable rules under the Securities Act of 1933, as amended. However, we may not be able to raise additional funds on favorable terms, or at all. Conditions in the credit markets and the financial services industry may make equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants, such as limitations on our ability to incur additional indebtedness and other operating restrictions that could adversely impact our ability to conduct our business.

In October 2016, we also entered into an At-The-Market Issuance Sales Agreement, or the ATM Agreement, with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.), or BP, under which we may issue and sell up to $10.0 million of shares of our common stock from time to time. As of October 27, 2017, we had sold 1,509,370 shares of our common stock under the ATM Agreement and have received gross proceeds of approximately $4.3 million. BP is not obligated to sell any shares that we may request to be sold, and any attempt to sell shares under this facility, if made, may not be successful or generate sufficient proceeds to meet our capital requirements.

If we are unable to obtain additional funds, we may have to scale back our development of new products, reduce our workforce or license to others products or technologies that we otherwise would seek to commercialize ourselves. The amount of money we may need would depend on many factors, including:

- The progress of our research and development programs;
- The scope and results of our preclinical studies and clinical trials;
- The amount of our legal expenses and any settlement or damages payments associated with litigation; and
- The time and costs involved in: obtaining necessary regulatory approvals; filing, prosecuting and enforcing patent claims; scaling up our manufacturing capabilities; and the commercial arrangements we may establish.

We may be unable to maintain compliance with the NASDAQ Marketplace Rules which could cause our common stock to be delisted from the NASDAQ Capital Market. This could result in the lack of a market for our common stock, cause a decrease in the value of an investment in us, and adversely affect our business, financial condition and results of operations.

Our common stock is currently listed on the NASDAQ Capital Market. To maintain the listing of our common stock on the NASDAQ Capital Market, we are required to meet certain listing requirements, including, among others, either: (i) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least $1 million and stockholders' equity of at least $2.5 million; or (ii) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least $1 million and a total market value of listed securities of at least $35 million. As of October 27, 2017, the closing sale price per share of our common stock was $2.18, the total market value of our publicly held shares of our common stock (excluding shares held by our executive officers, directors and 10% or more stockholders) was approximately $22.7 million and the total market value of our listed securities was approximately $27.5 million. There is no assurance that we will continue to meet the minimum closing price requirement and other listing requirements. As of September 30, 2017,

we had stockholders' equity of approximately $37.7 million. Although NASDAQ may provide us with a compliance period in which to regain compliance with the listing requirements, we cannot assure you that we would be able to regain compliance within the period provided by NASDAQ.

In the event that our common stock is delisted from NASDAQ and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business” in this prospectus or the documents incorporated herein by reference. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical trials;
- our estimates regarding anticipated operating losses, capital requirements and needs for additional funds;
- our ability to obtain funding for our operations beyond this offering when needed and to continue our research and development programs;
- our plans to develop and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the safety and efficacy of our product candidates;
- the anticipated regulatory pathways for our product candidates;
- our ability to successfully complete preclinical and clinical development of, and obtain regulatory approval of our product candidates and commercialize any approved products on our expected timeframes or at all;