VICAL INC

FORM 8-K
(Current report filing)

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Address	10390 PACIFIC CENTER COURT . SAN DIEGO, CA 92121-4340
Telephone	858-646-1100
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Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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 (Date of earliest event reported): **November 1, 2011**

Vical Incorporated

(Exact name of registrant as specified in its charter)

Delaware	**000-21088**	**93-0948554**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

10390 Pacific Center Court **San Diego, California**	**92121-4340**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(858) 646-1100**

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 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 2.02. Results of Operations and Financial Condition.

On November 1, 2011, Vical Incorporated issued a press release announcing, among other things, its unaudited financial results for the three months and nine months ended September 30, 2011. A copy of the press release is attached as Exhibit 99.1 to this Current Report.

The information in this Item 2.02, and Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release issued by Vical Incorporated on November 1, 2011.

SIGNATURES

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

Vical Incorporated

Date: November 1, 2011

By: /s/ JILL M. BROADFOOT
Jill M. Broadfoot
Senior Vice President, Chief Financial Officer and Secretary

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press release issued by Vical Incorporated on November 1, 2011.

Vical Reports Third Quarter 2011 Financial Results and Progress in Key Development Programs

SAN DIEGO, Nov. 1, 2011 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL) today reported financial results for the three months and nine months ended September 30, 2011. Revenues were $26.6 million for the third quarter of 2011 compared with $2.3 million for the third quarter of 2010, primarily as a result of the recognition of $25.1 million of license revenue for TransVax™, Vical's therapeutic vaccine designed to control cytomegalovirus (CMV) reactivation in transplant recipients.

During the third quarter of 2011, Vical and Astellas Pharma Inc. entered into exclusive worldwide license agreements to develop and commercialize TransVax™. The companies expect to begin a multinational Phase 3 registration trial of TransVax™ in hematopoietic stem cell transplant (HSCT) recipients as well as a Phase 2 trial in solid organ transplant (SOT) recipients in the first half of 2012.

Under the agreements, Astellas will be responsible for further development and commercialization, including all costs. Vical has an option to co-promote TransVax™ in the United States. Vical will provide assistance to Astellas with TransVax™-related manufacturing, regulatory and certain development activities, for which Astellas will reimburse all of Vical's future costs, including personnel and external expenses. Vical received $25 million upfront and will receive an additional $10 million upon finalization of the Phase 3 trial design, with potential total upfront and milestone payments through commercial launch of up to $130 million and double-digit royalties on net sales.

This development had a significant positive impact on Vical's third quarter financial results and is expected to continue to contribute to future financial results. Vical also reported progress during the third quarter in its Phase 3 Allovectin ® immunotherapy program for metastatic melanoma and in its preclinical herpes simplex type 2 (HSV-2) vaccine program, as detailed below.

Operating expenses were $10.2 million for the third quarter of 2011 compared with $9.1 million for the third quarter of 2010. Net income was $16.4 million, or $0.23 per basic share, for the third quarter of 2011, compared with a net loss of $6.8 million, or $0.12 per basic share, for the third quarter of 2010.

Revenues were $28.1 million for the first nine months of 2011 compared with $5.8 million for the first nine months of 2010, primarily as a result of the TransVax™ license. The net loss was $0.7 million, or $0.01 per share, for the first nine months of 2011, compared with a net loss of $23.6 million, or $0.42 per share, for the first nine months of 2010.

Vical had cash and investments of approximately $62 million at September 30, 2011, and expects to end the year with cash and investments of $53 million to $56 million.

Recent development highlights include:

Allovectin ®

The company presented encouraging animal data at a National Cancer Institute immunotherapy conference demonstrating a synergistic (more than additive) reduction of tumor growth and a positive trend in survival using a combination of the company's Allovectin ® immunotherapy with an anti-CTLA-4 antibody. The synergy became evident about 12 days after treatment initiation, suggesting a likely two-step process in which Allovectin ® first directs T cells to target the melanoma tumor and anti-CTLA-4 antibody then maximally activates these T cells. The study was conducted in a well-accepted melanoma mouse model using a standard mouse equivalent of human anti-CTLA-4 antibodies such as ipilimumab.

Herpes Simplex Type 2 (HSV-2) Vaccine

The company presented data at an international vaccine conference showing that its Vaxfectin ® -formulated plasmid DNA vaccines against HSV-2 provided complete protection in guinea pigs against both primary and recurrent HSV-2 disease. The vaccines also significantly reduced genital lesion recurrence and viral shedding as well as latent infection in the central nervous system. These data expanded on previous results from repeated studies in mice showing that the vaccines provided complete protection against lethal challenge, provided sterilizing immunity and inhibited viral counts at both the primary and latent infection sites. These results are among the best ever seen with a herpes vaccine in such a therapeutic model.

Anticipated program highlights include:

Allovectin ®

In the company's Phase 3 registration trial of Allovectin ® in patients with metastatic melanoma, enrollment was completed in February 2010. The protocol allows a maximum two-year treatment and follow-up period for the primary endpoint (response rate at 24 weeks or more after randomization), so the last patients must complete treatment by February 2012. Data collection and independent adjudication for the primary endpoint is expected to require several months. The secondary endpoint (overall survival) will continue to be monitored during the primary

endpoint adjudication process. Top-line data for both endpoints is expected in the second quarter of 2012.

TransVax™

Astellas expects to initiate a pivotal, multinational Phase 3 trial of TransVax™ for hematopoietic stem cell transplant recipients, and a Phase 2 efficacy trial of TransVax™ for solid organ transplant recipients, both in the first half of 2012.

Collategene™

AnGes expects to initiate a pivotal, multinational Phase 3 clinical trial of its Collategene™ angiogenesis product for patients with advanced peripheral arterial disease in 2012.

Conference Call

Vical will conduct a conference call and webcast today, November 1, at noon Eastern Time, to discuss with invited analysts and institutional investors the company's financial results and program updates. The call and webcast are open on a listen-only basis to any interested parties. To listen to the conference call, dial in approximately ten minutes before the scheduled call to (719) 325-2383 (preferred), or (888) 515-2880 (toll-free), and reference confirmation code 1312814. A replay of the call will be available for 48 hours beginning about two hours after the call. To listen to the replay, dial (719) 457-0820 (preferred) or (888) 203-1112 (toll-free) and enter replay passcode 1312814. The call also will be available live and archived through the events page at www.vical.com. For further information, contact Vical's Investor Relations department by phone at (858) 646-1127 or by e-mail at ir@vical.com.

About Vical

Vical researches and develops biopharmaceutical products based on its patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases. Potential applications of the company's DNA delivery technology include DNA vaccines for infectious diseases or cancer, in which the expressed protein is an immunogen; cancer immunotherapeutics, in which the expressed protein is an immune system stimulant; and cardiovascular therapies, in which the expressed protein is an angiogenic growth factor. The company is developing certain infectious disease vaccines and cancer therapeutics internally. In addition, the company collaborates with major pharmaceutical companies and biotechnology companies that give it access to complementary technologies or greater resources. These strategic partnerships provide the company with mutually beneficial opportunities to expand its product pipeline and address significant unmet medical needs. Additional information on Vical is available at www.vical.com.

The Vical Incorporated logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=5768

Forward-Looking Statements

This press release contains forward-looking statements subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include net cash use guidance, as well as anticipated developments in independent and collaborative programs, including the initiation and completion of clinical trials. Risks and uncertainties include whether the Astellas partnership will contribute to future financial results in the manner expected; whether Vical or others will continue development of Allovectin ®, TransVax™, Collategene™, the HSV-2 vaccine, or any other independent or collaborative programs; whether the synergistic effect with anti-CTLA-4 treatment demonstrated in mouse studies will be confirmed in humans; whether Vical or others will advance the HSV-2 vaccine candidate into human clinical testing; whether preclinical results will be predictive of results in human clinical testing; whether Vical will complete treatment and follow-up for the primary response rate endpoint in the company's Phase 3 trial of Allovectin ® by February 2012 and release of top-line data in the second quarter of 2012, if at all; whether Astellas will initiate the planned trials of TransVax™ in the first half of 2012, if at all; whether AnGes will initiate the planned trial of Collategene™ in 2012, if at all; whether Vical will achieve levels of revenues and control expenses to meet its financial projections; whether any product candidates will be shown to be safe and efficacious in clinical trials; the timing of clinical trials; whether Vical or its collaborative partners will seek or gain approval to market any product candidates; and additional risks set forth in the company's filings with the Securities and Exchange Commission. These forward-looking statements represent the company's judgment as of the date of this release. The company disclaims, however, any intent or obligation to update these forward-looking statements.

VICAL INCORPORATED

Selected Condensed Financial Information (Unaudited)

Statements of Operations	Three Months Ended Sept. 30,		Nine Months Ended Sept. 30,	
(in thousands, except per share amounts)	2011	2010	2011	2010
Revenues:				
Contract and grant revenue	$ 1,360	$ 1,573	$ 2,607	$ 3,538

License and royalty revenue	25,259	684	25,479	2,257
Total revenues	26,619	2,257	28,086	5,795
Operating expenses:				
Research and development	5,505	4,658	14,004	14,723
Manufacturing and production	2,343	2,307	7,697	8,543
General and administrative	2,379	2,102	7,161	6,473
Total operating expenses	10,227	9,067	28,862	29,739
Income (loss) from operations	16,392	(6,810)	(776)	(23,944)
Net investment and other income (expense)	39	43	107	319
Net income (loss)	$ 16,431	$ (6,767)	$ (669)	$ (23,625)
Basic net income (loss) per share	$ 0.23	$ (0.12)	$ (0.01)	$ (0.42)
Diluted net income (loss) per share	$ 0.22	$ (0.12)	$ (0.01)	$ (0.42)
Weighted average shares used in basic net income (loss) calculation	72,075	56,745	71,987	56,155
Weighted average shares used in diluted net income (loss) calculation	73,739	56,745	71,987	56,155

Balance Sheets		
(in thousands)	September 30, 2011	December 31, 2010
Assets:		
Cash, cash equivalents, and marketable securities, including restricted	$ 55,632	$ 55,268
Other current assets	2,642	940
Total current assets	58,274	56,208
Long-term investments	5,915	5,434
Property and equipment, net	6,654	7,560
Other assets	3,204	3,705
Total assets	$ 74,047	$ 72,907
Liabilities and stockholders' equity:		
Current liabilities	$ 5,484	$ 6,334
Long-term obligations	2,036	2,211
Stockholders' equity	66,527	64,362
Total liabilities and stockholders' equity	$ 74,047	$ 72,907

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