

Cobalis Corp
Form SB-2
February 20, 2007

U. S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM SB-2
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Cobalis Corp.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction
of incorporation or organization)

2834

(Primary Standard Industrial
Classification Code Number)

91-1868007

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

2445 McCabe Way, Suite 150, Irvine, California 92614

(Address of registrant's principal executive offices) (Zip Code)

(949) 757-0001

(Registrant's Telephone Number, Including Area Code)

Gerald Yakatan, Ph.D.

Cobalis Corp.

2445 McCabe Way, Suite 150

Irvine, California 92614

Telephone; 949-757-0001

(Name, Address and Telephone Number of Agent for Service)

Approximate date of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

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. ☐ _____

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. ☐ _____

CALCULATION OF REGISTRATION FEE

Title of each class	Amount			Amount of
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of securities to be registered	to be registered	Proposed maximum offering price per share (2)	Proposed maximum aggregate offering price	registration fee
Common Stock, \$.001 par value	10,583,737 ⁽¹⁾	\$0.92	\$9,737,038.04	\$1,041.86
Total	10,583,737	\$0.92	\$9,737,038.04	\$1,041.86

(1) Represents 10,583,737 shares of common stock issuable pursuant to the terms of a securities purchase agreement with Cornell Capital Partners, LP dated December 20, 2006.

(2) Estimated solely for the purpose of estimating the registration fee pursuant to Rule 457(c) promulgated pursuant to the Securities Act of 1933, on the basis of \$0.92 per share, the average of the bid and ask price of the Registrant's common stock as reported on the Over-The-Counter Bulletin Board on February 14, 2007.

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 this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Preliminary Prospectus
Cobalis Corp., a Nevada corporation

10,583,737 Shares of Common Stock

This prospectus relates to 10,583,737 shares of common stock of Cobalis Corp., pursuant to the terms of a securities purchase agreement by and between us and Cornell Capital Partners, LP ("Cornell Capital"), dated December 20, 2006. The securities purchase agreement incorporated the following instruments:

- a convertible debenture for \$2,500,000;
- two convertible debentures issuable upon the attainment of certain milestones, each for \$675,000; and
- four separate warrant agreements.

The securities were and will be acquired by the selling security holder in private placement transactions which we believe are exempt from the registration and prospectus delivery requirements of the Securities Act of 1933. The selling security holder will offer and sell the shares at prevailing market prices or privately negotiated prices. We will not receive any of the proceeds from the sale of those shares being offered by the selling shareholder. However, in the event that the above warrants are exercised, we will receive proceeds in the approximate amount of \$5,500,000, unless the above warrants are exercised on a "cashless" basis.

Our common stock is currently eligible for quotation on the Over-The-Counter Bulletin Board. Our trading symbol is "CLSC.OB".

SEE "RISK FACTORS" ON PAGES 7 THROUGH 17 FOR FACTORS TO BE CONSIDERED BEFORE PURCHASING SHARES OF OUR COMMON STOCK.

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 INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. WE WILL CAUTION THE SELLING SECURITY HOLDER THAT IT IS NOT TO 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 OR OTHER JURISDICTION WHERE THE OFFER OR SALE OF THESE SECURITIES IS NOT PERMITTED.

The date of this prospectus is February 20, 2007. Subject to completion.

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Dealer Prospectus Delivery Obligation

Until _____, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligations to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

Prospectus Summary

Our Business:

We were incorporated in Nevada on September 26, 1997, as Aztec Ventures, Inc. Our principal business address is 2445 McCabe Way, Suite 150, Irvine, California 92614. Our telephone number is (949)757-0001.

We are a development stage company focused on the development and commercialization of our anti-allergy medication, PreHistin™. We anticipate that our initial patented product candidate, PreHistin™, could create a unique niche within the allergy relief category because it is intended to prevent allergy symptoms by mitigating histamines from being over-produced, as opposed to conventional antihistamine products that work by reacting only after the overproduction of histamines has already occurred. We hope to obtain data from our recently completed twin Phase III pivotal trials in 1,551 seasonal ragweed allergy patients that would support a New Drug Application (“NDA”) and FDA approval to market PreHistin™ over-the-counter in the United States. If that is the case, we would anticipate completing the necessary steps to file an NDA in the second half of calendar 2007, followed by an FDA review period of up to twelve months. If approved, a product launch would typically follow within three months of such an approval. We are currently developing PreHistin™ only for use with seasonal allergies. Currently, we have no products for sale nor have we generated any product revenues to date.

In July 2003, we entered into an Agreement and Plan of Merger to acquire, as an operational subsidiary, BioGentec Incorporated, which was incorporated in Nevada on November 21, 2000, and whose business we adopted. In 2004, we changed our name to Cobalis Corp. BioGentec Incorporated was subsequently dissolved.

Summary financial information:

The summary financial information set forth below is derived from the more detailed financial statements appearing elsewhere in this Form SB-2. We have prepared our financial statements contained in this Form SB-2 in accordance with accounting principles generally accepted in the United States. All information should be considered in conjunction with our financial statements and the notes contained elsewhere in this Form SB-2. Note that during 2003, we changed our fiscal year end from December 31st to March 31st.

	For the nine months ended December 31, 2006 (unaudited)	For the year ended March 31, 2006 (audited)
Income Statement		
	\$	\$
Gross Loss	0	0
Loss from Operations	(9,703,638)	(5,890,255)
Net Loss	(13,319,827)	(6,603,454)
Net Loss Per Share	(0.42)	(0.26)

	December 31, 2006 (unaudited)	March 31, 2006 (audited)
Balance Sheet		
	\$	\$
Total Assets	2,631,591	1,180,527
Total Liabilities	(16,697,371)	(8,865,112)
Stockholders' Deficit	(14,508,280)	(8,569,585)

Number of shares being offered:

We are registering 10,583,737 shares which are issuable to Cornell Capital Partners, LP ("Cornell Capital"), as described herein.

Number of shares outstanding:

As of February 20, 2007, there were 35,824,672 shares of our \$0.001 par value common stock issued and outstanding. We also have 500 shares of our preferred stock outstanding, along with 5,991,667 options to purchase shares of our common stock and 6,094,844 warrants to purchase shares of our common stock. We do not have any other debentures, notes, or similar instruments outstanding, which are convertible to shares of our common stock.

Estimated use of proceeds:

We will not receive any of the proceeds from the sale of those shares being offered. However, if the warrants are exercised, we could receive proceeds of up to \$5,500,000. We intend to use the proceeds of that exercise, should it occur, for funding our clinical trials and for working capital.

Forward Looking Statements

INFORMATION IN THIS PROSPECTUS CONTAINS "FORWARD LOOKING STATEMENTS" WHICH CAN BE IDENTIFIED BY THE USE OF FORWARD-LOOKING WORDS SUCH AS "BELIEVES", "ESTIMATES", "COULD", "POSSIBLY", "PROBABLY", "ANTICIPATES", "ESTIMATES", "PROJECTS", "EXPECTS", "MAY", OR "SHOULD" OR OTHER VARIATIONS OR SIMILAR WORDS. NO ASSURANCES CAN BE GIVEN THAT THE FUTURE RESULTS ANTICIPATED BY THE FORWARD-LOOKING STATEMENTS WILL BE ACHIEVED. THE FOLLOWING MATTERS CONSTITUTE CAUTIONARY STATEMENTS IDENTIFYING IMPORTANT FACTORS WITH RESPECT TO THOSE FORWARD-LOOKING STATEMENTS, INCLUDING CERTAIN RISKS AND UNCERTAINTIES THAT COULD CAUSE ACTUAL RESULTS TO VARY MATERIALLY FROM THE FUTURE RESULTS ANTICIPATED BY THOSE FORWARD-LOOKING STATEMENTS. AMONG THE KEY FACTORS THAT HAVE A DIRECT BEARING ON OUR RESULTS OF OPERATIONS ARE THE COSTS AND EFFECTIVENESS OF OUR OPERATING STRATEGY. OTHER FACTORS COULD ALSO CAUSE ACTUAL RESULTS TO VARY MATERIALLY FROM THE FUTURE RESULTS ANTICIPATED BY THOSE FORWARD-LOOKING STATEMENTS.

Risk Factors

In addition to the other information in this prospectus, the following risk factors should be considered carefully in evaluating our business before purchasing any of our shares of common stock. A purchase of our common stock is speculative in nature and involves many risks. No purchase of our common stock should be made by any person who is not in a position to lose the entire amount of his or her investment.

Risks Related to our Business:

Our auditors have expressed substantial doubt regarding our ability to continue operations as a “going concern.” We currently have no product revenues and will need to raise additional capital to operate our business.

To date, we have generated no product or partnership revenues. We have not completed the development of our products and we can not be assured of generating partnership or product revenues. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures almost exclusively from obtaining additional financing or from our cash on hand. As of December 31, 2006, we had \$1,684,580 in cash resources as a result of recently having concluded a financing arrangement with Cornell Capital for proceeds to us of \$2,500,000 in December 2006, less certain costs and fees, and an aggregate total of up to \$3,850,000 as part of the total arrangement, less certain costs and fees. However, we will need to seek additional sources of financing, which may not be available on favorable terms, if at all. We may also face certain penalties if we are unable to comply with requirements of the agreement with Cornell Capital. If this registration statement is not filed nor declared effective by the required dates, then we could face certain liquidated damages payable to Cornell Capital, which may include a monthly cash penalty of 1% of the liquidated value of the outstanding debentures payable for no more than 15 months. The debentures are also secured by all our assets and by a pledge of 8,400,000 of the shares of our common stock which are beneficially owned by Radul Radovich, one of our directors, which comprises approximately 23.6% of our currently issued and outstanding common stock.

Unless we receive approval from the U.S. Federal Drug Administration ("FDA"), and other regulatory authorities for our PreHistinTM product, we will not be able to market our product as an FDA-approved anti-allergy medication. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete the necessary analysis of our recently concluded twin pivotal Phase III trials, or meet other requirements necessary to obtain approval of our initial product candidate, PreHistinTM from the FDA and other regulatory authorities. If we default on terms of the agreements with Cornell Capital, we could be required to pay cash penalties. In addition, without adequate funding to finance our activities, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. As a result, our auditors believe that substantial doubt exists about our ability to continue operations. If we are unable to raise additional financing that may be needed, it is possible we will never earn revenue and you could lose your entire investment.

We are not currently profitable and may never become profitable, which could lead to the failure of our business.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. From our inception to December 31, 2006, we have suffered cumulative net losses of \$37,243,607. Even if we succeed in developing and commercializing one or more of our products, we may incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to undertake development of our product, PreHistinTM;
- seek regulatory approvals for our product;

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- implement additional internal systems and infrastructure;
 - prosecute our intellectual property portfolio:
- lease additional or alternative office facilities as they become necessary; and
 - hire additional personnel.

We also expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our common stock or lead to our dissolution.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits and FDA approval does not guarantee that our products will be immune from such lawsuits.

The testing and marketing and sales of medicinal products entail an inherent risk of product liability. In the event that we obtain FDA approval for our products and are able to market and sell our products, such approval will not preclude the possibility that our products will not subsequently lose such approval or become the subject of product liability litigation. Recent examples of such cases are products that previously had full FDA approval for marketing and sales, such as Vioxx, which was removed from the market and is now the subject of litigation and Celebrex, which still may be sold, though no longer advertised. In the event that we obtain FDA approval for our products and thereafter commence commercial sales and marketing, our products may eventually become the subject of product liability litigation. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with corporate collaborators. We carried clinical trial insurance for our twin Phase III trials, but do not yet have product liability insurance. In the event that we are able to market and sell our product candidate in the future, we, or any corporate collaborators may not be able to obtain product liability insurance at a reasonable cost, if at all. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. Our inability to pay for uninsured claims could force us to curtail our ability to begin producing revenue and lead to our dissolution.

We may not obtain the necessary U.S. or worldwide regulatory approvals to commercialize our product candidate. Our business may fail if we are unable to obtain such approvals.

We will need FDA approval to commercialize our initial product candidate, PreHistinTM as an FDA-approved pharmaceutical in the U.S. as well as approvals from equivalent regulatory authorities in foreign jurisdictions to commercialize our products as a pharmaceutical in those jurisdictions. In order to obtain FDA approval of any of our product candidates, we must submit to the FDA a New Drug Application, ("NDA"), demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as pre-clinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in a drug that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional pre-clinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidate;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject our NDA. We cannot be sure that we will ever obtain regulatory clearance for our product candidate, PreHistinTM. Failure to obtain FDA approval of our

product candidate will severely undermine our business by reducing our number of salable products and, therefore, corresponding partnership and/or product revenues.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize our product. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described immediately above.

Our primary product candidate is in Phase III of clinical trials. Clinical trials are very expensive, time-consuming and difficult to design and implement, and there is no guarantee that our primary product candidate will be approved for commercial sales. We will rely on commercial sales of this product and have no other source of generating revenues.

Our product candidate, PreHistin™, recently completed patient dosing in twin pivotal Phase III trials with 1,551 seasonal ragweed allergy patients. Phase III trials are generally considered the last step in clinical drug development before submission of a New Drug Application (NDA). The filing of an NDA is how we or a partner will request marketing approval from the FDA and similar regulatory agencies outside the USA.

We have submitted an Investigational New Drug application (IND) to the FDA which has been assigned the IND number 68,994. Our regulatory team and our clinical research organization (CRO), DataMed Devices, Inc. located in Lake Forest, California, are working with the clinical study sites to collect and audit the patient data from our recently completed twin Phase III trials prior to locking the data and calculating if the trials met their primary end point of statistically significant lowering of patients' Total Nasal Symptom Score (TNSS) as well as other safety and efficacy parameters.

Additionally, we plan to conduct pharmacokinetics and animal studies on the final clinical formulation. Our primary product is provisionally named PreHistin™, a name which must still be approved by the FDA and possibly by foreign regulatory agencies.

Although we cannot predict with any certainty if or when the studies will be completed (a situation that could negatively impact our ability to earn revenues), we believe that all of the above studies will essentially be completed during calendar 2007.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. We estimate that completing the analysis of our twin Phase III trials for PreHistin™ in seasonal ragweed allergy patients and completing the necessary studies to submit an NDA will take at least several months to complete. Failure can occur as a result of cost overruns or other financial considerations. Furthermore, we could encounter problems that cause us to abandon or repeat clinical trials. The completion of clinical trials may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators or our CRO or other parties assisting with the clinical trials to follow our clinical protocols.

As of the date of this registration statement, our clinical trials are completed; however, we must finish the process of collecting and analyzing the resulting data and, if that data is supportive, complete the necessary steps to prepare and file an NDA with the FDA. If we are unable to finance the completion of these steps, our ability to earn revenue will be negatively impacted. Moreover, negative results from clinical trials could destroy our ability to partner or market and sell our product candidate as an FDA-approved drug. As of the date of this registration statement, we do not have adequate funds to complete all the steps that will be necessary to complete and file an NDA. There is no guarantee that the results of our clinical trials will be positive, or, if they are, that we will be able to prepare and file an NDA, or

that the FDA will approve our product candidate for marketing and sale as we propose.

The results of our clinical trials may not support our product candidate claims, which may make it difficult for us to sell or partner our first planned product, our only source of revenues. Our business will fail if we are unable to earn revenues.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon the particular product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDA with the FDA and foreign regulatory agencies and, ultimately, harm our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials involve a relatively small patient population. Because of the small sample s