CHIMERIX INC
Form S-1
October 08, 2013

**As filed with the Securities and Exchange Commission on October 8, 2013**

**Registration No. 333-**

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

# FORM S-1

# REGISTRATION STATEMENT
# UNDER THE SECURITIES ACT OF 1933

# Chimerix, Inc.

(Exact Name of Registrant as Specified in Its Charter)

| Delaware | 2834 | 33-0903395 |
|---|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (Primary Standard Industrial Classification Code Number) | (I.R.S. Employer Identification Number) |

**2505 Meridian Parkway, Suite 340**
**Durham, NC 27713**
**(919) 806-1074**

(Address, Including Zip Code, and Telephone Number,
Including Area Code, of Registrant s Principal Executive Offices)

**Kenneth I. Moch**
**President and Chief Executive Officer**
**Chimerix, Inc.**
**2505 Meridian Parkway, Suite 340**
**Durham, NC 27713**
**(919) 806-1074**

(Name, Address, Including Zip Code, and Telephone Number,
Including Area Code, of Agent for Service)

*Copies to:*

Jason L. Kent, Esq.
Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121
(858) 550-6000

Timothy W. Trost
Senior Vice President, Chief Financial Officer and Corporate Secretary
Chimerix, Inc.
2505 Meridian Parkway, Suite 340
Durham, NC 27713
(919) 806-1074

Richard D. Truesdell, Jr., Esq.
Davis Polk & Wardwell LLP
450 Lexington Avenue
New York, NY 10017
(212) 450-4000

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. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) 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(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 registration 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.

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

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# 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, $0.001 par value per share | $ 50,000,000 | $ 6,440 |

(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 shares that the underwriters have the option to purchase to cover over-allotments, if any.

**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 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. Neither we nor the selling stockholders may 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 neither we nor the selling stockholders are soliciting offers to buy these securities in any state where the offer or sale is not permitted.

*PROSPECTUS (Subject to Completion)*
*Issued October 8, 2013*

***Shares***

***COMMON STOCK***

***The selling stockholders included in this prospectus are selling shares of common stock. We will not receive any proceeds from this offering. Our common stock is listed on the Nasdaq Global Market under the symbol CMRX. On October 7, 2013, the last reported sale price of our common stock on the Nasdaq Global Market was $21.91 per share.***

***We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.***

***Investing in our common stock involves risks. See Risk Factors beginning on page 9.***

***PRICE $ A SHARE***

| | ***Price to Public*** | ***Underwriting Discounts and Commissions[(1)]*** | ***Proceeds to Selling Stockholders*** |
|---|---|---|---|
| *Per Share* | *$* | *$* | *$* |
| *Total* | *$* | *$* | *$* |

(1) We have agreed to reimburse the underwriters for certain FINRA-related expenses. See Underwriters .

*The selling stockholders have granted the underwriters the right to purchase up to an additional shares of common stock to cover over-allotments.*

*The Securities and Exchange Commission and state securities regulators have not approved or disapproved these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.*

*The underwriters expect to deliver the shares of common stock to purchasers on , 2013.*

***MORGAN STANLEY*** ***COWEN AND COMPANY***

*, 2013*

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Neither we, the selling stockholders, nor any of the underwriters has authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we may have referred you in connection with this offering. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. Neither we, the selling stockholders nor any of the underwriters is making an offer to sell or seeking offers to buy these securities in any jurisdiction where or to any person to whom the offer or sale is not permitted. The information in this prospectus is accurate only as of the date on the front cover of this prospectus and the information in any free writing

prospectus that we may provide you in connection with this offering is accurate only as of the date of that free writing prospectus. Our business, financial condition, results of operations and future growth prospects may have changed since those dates.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

For investors outside the United States: neither we, the selling stockholders nor any of the underwriters has done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside of the United States.

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# PROSPECTUS SUMMARY

*This summary highlights information contained in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. You should read the entire prospectus carefully, especially Risk Factors and our financial statements and the related notes, before deciding to buy shares of our common stock. Unless the context requires otherwise, references in this prospectus to Chimerix , the Company , we , us and our refer to Chimerix, Inc.*

## Overview

Chimerix is a biopharmaceutical company committed to the discovery, development and commercialization of novel, oral antiviral therapeutics that are designed to transform patient care in areas of high unmet medical need. Our proprietary lipid technology has given rise to two clinical-stage compounds, brincidofovir (CMX001) and CMX157, which have demonstrated the potential for enhanced antiviral activity and safety in convenient, orally administered dosing regimens. We have worldwide rights to our lead product candidate, brincidofovir, and initiated the Phase 3 SUPPRESS trial for the prevention of cytomegalovirus (CMV) infection in hematopoietic cell transplant (HCT) recipients in the third quarter of 2013. We intend to develop brincidofovir as the first broad-spectrum antiviral for double-stranded DNA (dsDNA) viral infections. Our second clinical-stage compound, CMX157, is a Phase 1 product candidate for the treatment of HIV and was licensed to Merck, Sharp & Dohme Corp. (Merck) in 2012.

Brincidofovir is an orally administered nucleotide drug that utilizes our proprietary lipid technology to deliver high intracellular concentrations of a potent antiviral compound, cidofovir-diphosphate (CDV-PP). Following oral dosing, brincidofovir is absorbed through the gut, remains intact in the plasma, and is passively delivered into cells. Once inside cells, brincidofovir is converted into CDV-PP, which acts as an alternative substrate that interferes with viral replication. When CDV-PP is selected by critical enzymes as a substrate over the normal cellular substrate (i.e., nucleotides), the result is diminished viral replication.

Although brincidofovir and intravenous cidofovir (Vistide®) are both converted into CDV-PP once inside cells, Vistide requires high plasma concentrations to deliver a therapeutic level of cidofovir into cells, and has limited utility due to the risk of kidney damage.

The herpesvirus family includes CMV, Epstein-Barr virus (EBV), HHV-6 and other viruses commonly transmitted in childhood and early adulthood, and which establish latency, generally remaining dormant in individuals with a functioning immune system. However, in immunocompromised patients, such as HCT or solid organ transplant (SOT) recipients, CMV and other latent viral infections may reactivate, causing significant morbidity, mortality, graft rejection and facilitating co-infection with other opportunistic pathogens. CMV is the most common infectious pathogen in HCT, and can result in life-threatening pneumonia or other organ involvement, particularly in the first 100 days following transplant when the immune system is most vulnerable. In addition to potent activity against CMV and other herpesviruses, brincidofovir has shown broad-spectrum *in vitro* antiviral activity against all five families of dsDNA viruses that cause human disease: adenoviruses (AdV), polyomaviruses such as BK virus (BKV), papillomaviruses, orthopoxviruses, and herpesviruses.

In the post-transplant setting, there are three paradigms for addressing viral infections: prevention or universal prophylaxis, preemptive therapy, and treatment of disease. Prevention is the administration of an antiviral to at-risk patients to avoid reactivation of a latent virus or primary infection with a new virus. Preemptive therapy is the

initiation of antiviral(s) only after detection of a specific virus in the blood (viremia) in an asymptomatic patient, or other evidence of early infection. Treatment is the watch-and-wait approach of initiating antiviral therapy after the virus is detected in an organ system where clinical signs or symptoms are present.

No drugs are approved for prevention of CMV in HCT recipients, primarily due to the high threshold for safety and tolerability for a compound intended for use as universal prophylaxis across a broader population of at-risk patients. Currently available antivirals with anti-CMV activity are limited by significant renal and hematological side effects. We believe that a safe and well-tolerated antiviral with demonstrated efficacy in

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prevention settings would provide a new standard of care for immunocompromised patients. In HCT, a safe and effective therapy for CMV prevention could potentially replace the current practice of intensive monitoring for CMV viremia with initiation of anti-CMV preemptive therapy following detection. In addition, we believe that an antiviral with broad-spectrum activity could reduce the frequency of other dsDNA viral infections commonly encountered in these patients, and could provide measureable clinical and pharmacoeconomic benefits for patients and the health care system.

We demonstrated the potential clinical utility of brincidofovir in a 230-patient Phase 2 dose-escalation study for the prevention of CMV reactivation in HCT recipients. The results of this study were published in an article, entitled CMX001 to Prevent Cytomegalovirus Disease in Hematopoietic-Cell Transplantation, in the September 26, 2013 issue of the *New England Journal of Medicine* (N Engl J Med 369:1227-36). In this study, brincidofovir or placebo was administered to HCT recipients from stem cell engraftment through Week 13 post-transplant. A reduction of more than 50% in risk of CMV infection was observed for the subjects who received brincidofovir 100 mg twice weekly (BIW). Ten percent of subjects (five of 50 subjects) in the brincidofovir 100 mg BIW cohort met the primary endpoint, CMV disease or a positive quantitative blood test for CMV at the end of the dosing period, versus 37% of subjects (22 of 59 subjects) in the placebo cohort (p=0.002, where the p-value is the statistical probability of a result not due to chance alone). The dose-limiting toxicity of diarrhea was observed in a high proportion of subjects at the highest dose tested, brincidofovir 200 mg BIW, and was subsequently addressed with the addition of a Safety Monitoring and Management Plan (SMMP) incorporated in the final Phase 2 cohort and in subsequent studies. The SMMP has been included in the ongoing Phase 3 study of brincidofovir in CMV prevention in HCT recipients, SUPPRESS. There was no evidence of kidney, hematologic or bone marrow toxicity in the Phase 2 study at any dose tested.

The results of this Phase 2 study, together with brincidofovir s overall preclinical and clinical profile, which includes a safety database of more than 800 subjects exposed to brincidofovir in controlled and uncontrolled clinical studies, supported the progression to the Phase 3 SUPPRESS study of brincidofovir for the prevention of CMV infection in high-risk HCT recipients. The primary endpoint is a composite endpoint of either (i) CMV disease, or (ii) initiation of anti-CMV preemptive therapy triggered by a positive test for CMV in the blood (viremia), assessed through Week 24 post-transplant. We intend to enroll 450 high-risk (i.e., with latent CMV infection) HCT recipients who will be randomized to receive brincidofovir 100 mg BIW or placebo from the early post-transplant period until Week 14 post-transplant. Secondary endpoints include pharmacoeconomic data and the incidence of disease and reactivation of other herpesviruses such as HHV-6, as well as other dsDNA viruses such as AdV, and BKV.

We intend to submit a new drug application (NDA) under an accelerated approval pathway seeking regulatory approval to market brincidofovir in the United States and equivalent applications outside the United States. We have received Fast Track designation from the FDA for the CMV, AdV and smallpox indications for brincidofovir.

We believe that there is a significant commercial opportunity for an antiviral such as brincidofovir with broad-spectrum activity against dsDNA viruses. According to the Center for International Blood and Marrow Transplant Research and the Organ Procurement and Transplantation Network, more than 20,000 HCTs and 28,000 SOTs are performed annually in the United States, with similar numbers of transplants performed annually in Europe according to the European Group for Blood and Marrow Transplantation and the World Health Organization. More than 65% of stem cell transplant patients are at increased risk of CMV infection due to prior exposure to CMV defined by evidence of antibodies to CMV in the blood (i.e., CMV seropositivity). In individuals outside the transplant population, many factors are influencing the epidemiology of dsDNA viral infections, including the use of potent immunosuppressive therapies in autoimmune and other diseases. Since 2009, Chimerix has made brincidofovir available under expanded access regulations to over 80 transplant centers worldwide for the treatment of over 430 patients with life-threatening dsDNA viral infections and no satisfactory alternative treatment options, reflecting the

high unmet medical need in this therapeutic area. Our brincidofovir Compassionate Use Program refers to the emergency investigational new drug (EIND) program which provided treatment to 230 individuals and Study 350, the expanded access study which enrolled 215 patients meeting similar inclusion criteria as the EINDs.

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If brincidofovir obtains regulatory approval, we intend to build our own sales force and to commercialize brincidofovir. In the United States, approximately 200 institutions perform transplants, of which approximately 75% perform HCT and 75% perform SOT. As a result, we believe we can commercialize brincidofovir for prevention of CMV in HCT recipients in the United States and Canada with a relatively small marketing and specialty sales force infrastructure of approximately 50 employees.

We are also evaluating the potential for brincidofovir for AdV infection, an often-fatal viral infection in immunocompromised patients. In September 2013, we presented encouraging results from a Phase 2 study of brincidofovir in the setting of preemptive therapy for AdV at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). With little known about the epidemiology of AdV infections, this first interventional trial in AdV infection was designed to mirror the current standard in CMV of initiation of therapy at the time of first detection of replicating virus in the blood. Allogeneic HCT recipients who received brincidofovir 100 mg BIW demonstrated decreased levels of AdV in the blood and a potential benefit in reduced disease progression and all-cause mortality, compared to subjects who received placebo or brincidofovir once weekly (QW). Intent-to-treat analyses as well as exploratory analyses in specific patient groups were consistent in trends favoring the brincidofovir BIW regimen over placebo, although statistical significance was not established in this small study. There were no new safety concerns identified in this trial, and very few temporary or permanent discontinuations of study drug for GI related adverse events were reported, demonstrating the successful implementation of the SMMP. As multiple dsDNA viral infections were noted in these pediatric and high-risk adult HCT recipients, future clinical development may include a study of brincidofovir for prevention of AdV and other dsDNA viral infections. Development of brincidofovir for dsDNA viral infections in SOT recipients and other immunocompromised patients is also under discussion.

CMX157, our second clinical stage compound, is an oral nucleotide compound in Phase 1 development for the treatment of HIV infection. In July 2012, we granted Merck an exclusive worldwide license to develop and commercialize CMX157 for HIV or other indications. Merck is responsible for all development and marketing activities for CMX157 on a worldwide basis.

# Our Strategy

Our strategy is to discover, develop, and commercialize novel oral antiviral therapeutics in areas of significant unmet medical need. Key elements of our strategy include:

advancing brincidofovir through Phase 3 clinical development for the prevention of CMV infection in high-risk patients following HCT;

expanding brincidofovir s ability to address the unmet medical need in pediatric HCT recipients;

leveraging the broad-spectrum profile of brincidofovir in other indications including AdV and/or BKV, and in other patient populations, such as SOT recipients and patients receiving therapies which result in compromised immune systems;

obtaining Accelerated Approval and Traditional Approval for marketing of brincidofovir for the prevention of CMV in the United States, and equivalent health authority approvals in Canada and key European markets;

commercializing brincidofovir with a targeted marketing and specialty sales force;

continuing development of brincidofovir as a potential medical countermeasure against smallpox, subject to continuing government support, including from the Biomedical Advanced Research and Development Authority (BARDA); and

advancing compounds from the Chimerix Chemical Library through IND-enabling studies and potential clinical development and/or partnerships.

We may enter into additional collaborations to implement our strategy.

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# Our Product Candidates

The following chart depicts our product candidates, their indications, and their current stage of development:

# Risks Associated with Our Business

Our business is subject to numerous risks, as more fully described in the section entitled Risk Factors immediately following this prospectus summary. You should read these risks before you invest in our common stock. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy. In particular, risks associated with our business include:

We have incurred significant losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability. We have never generated any revenue from sales of products and may never be profitable. We may need to raise additional capital in connection with our continuing operations, which may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates.

We depend on the success of our lead product candidate, brincidofovir, which is still in clinical development, and may not obtain regulatory approval or be successfully commercialized.

We rely on third party manufacturers to produce our preclinical and clinical drug supplies, and we intend to rely on third parties to produce commercial supplies of any approved product candidates.

If we are unable to obtain or protect intellectual property rights related to our products and product candidates, we may not be able to compete effectively in our market.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

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# Corporate Information

We were incorporated in Delaware in April 2000. Our principal executive offices are located at 2505 Meridian Parkway, Suite 340, Durham, North Carolina 27713, and our telephone number is (919) 806-1074. Our corporate website address is *www.chimerix.com*. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

We have obtained a registered trademark for Chimerix® in the United States. This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of (a) December 31, 2018, (b) the last day of the fiscal year in which we have total annual gross revenue of at least $1.0 billion, (c) the last day of the fiscal year in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (d) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We refer to the Jumpstart Our Business Startups Act of 2012 in this prospectus as the JOBS Act, and references in this prospectus to emerging growth company shall have the meaning associated with it in the JOBS Act.

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# THE OFFERING

| | |
|---|---|
| Common stock offered by the selling stockholders | shares |
| Common stock to be outstanding after this offering | shares |
| Over-allotment option | The selling stockholders have granted to the underwriters the option, exercisable for 30 days from the date of this prospectus, to purchase up to additional shares of common stock. |
| Use of proceeds | The selling stockholders will receive all of the net proceeds from the offering and we will not receive any proceeds from the sale of shares in this offering. 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. |
| Nasdaq Global Market symbol | CMRX |

The number of shares of our common stock to be outstanding after this offering is based on 25,974,809 shares of common stock outstanding as of September 30, 2013, and excludes:

- shares of common stock issuable upon the exercise of outstanding stock options as of September 30, 2013, at a weighted-average exercise price of $ per share;
- 102,547 shares of common stock issuable pursuant to outstanding restricted stock units as of September 30, 2013;
- 1,343,760 shares of common stock issuable upon the exercise of outstanding warrants as of September 30, 2013, at a weighted-average exercise price of $7.25 per share;
- 704,225 shares of common stock reserved for future issuance under our 2013 employee stock purchase plan (the ESPP); and
- 1,691,272 shares of common stock reserved for future issuance under our 2013 equity incentive plan (the 2013 plan).

Unless otherwise indicated, all information contained in this prospectus assumes:

- no exercise by the underwriters of their over-allotment option to purchase up to an additional shares of our common stock from the selling stockholders; and
- the issuance of shares of our common stock to a selling stockholder upon the exercise of stock options subsequent to September 30, 2013 that will be sold in this offering.

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# SUMMARY FINANCIAL DATA

The following summary financial data should be read together with our financial statements and related notes, Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future and results of interim periods are not necessarily indicative of the results for the entire year.

We derived the following summary statement of operations data for the years ended December 31, 2010, 2011 and 2012 and balance sheet data as of December 31, 2011 and 2012 from our audited financial statements and related notes appearing elsewhere in this prospectus. We derived the sum