INNOVUS PHARMACEUTICALS, INC. Form 424B4 October 15, 2012

> Filed pursuant to Rule 424(b)(4) Registration Statement No. 333-183141

# **PROSPECTUS**

# 150,580 Shares of Common Stock

This prospectus relates to the offer for sale of up to a total of 150,580 shares of our common stock that may be sold from time to time by certain existing stockholders named in this prospectus and their successor and assigns. The shares of common stock to be sold by the selling stockholders were acquired in June 2012 in connection with a private placement to accredited investors and a conversion of a debt instrument.

The shares offered for resale by this prospectus were issued to the applicable selling stockholders in private transactions completed prior to the filing of this registration statement, of which this prospectus is a part. This offering is not being underwritten. We will not receive any proceeds from the sale of shares in this offering.

The selling stockholder, to the extent a public market exists at such time, may offer their common stock from time to time through public transactions at prevailing market prices, at prices related to prevailing market prices, or through private transactions at privately negotiated prices. We have agreed to pay all costs and expenses of registering this offering of securities.

Our common stock is included for quotation on the OTCBB under the symbol INNV. There is limited trading in our common stock. On August 6, 2012, the most recent day that our stock traded, the last reported price per share of our common stock was \$2.25. You are urged to obtain current market quotations of our common stock before purchasing any of the shares being offered for sale pursuant to this prospectus.

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act ( JOBS Act ) and as such we will be subject to reduced public company reporting requirements.

Investing in our common stock involves substantial risks. You should carefully consider the matters discussed under Risk Factors beginning on page 5 of this prospectus.

Neither the Securities and Exchange Commission (SEC) nor any state securities commission has approved or disapproved these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is October 9, 2012.

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You should rely only on the information contained or incorporated by reference in this prospectus and any free-writing prospectus prepared by or on behalf of us or to which we have referred you. We are an emerging growth company under the federal securities laws and will therefore be subject to reduced public company reporting requirements. We have not authorized anyone to provide additional or different information. The information contained in this prospectus is accurate as of the date of this prospectus regardless of the delivery of this prospectus or any sale of securities contemplated hereby.

For convenience trademarks, service marks and trade names referred to in this prospectus may be without appropriate symbols, but such omissions are not intended to indicate in any way that the owner will not assert under applicable law to the fullest extent such owner's rights to these trademarks, service marks and trade names. This prospectus contains additional trade names, trademarks and service marks of other companies which to our knowledge are the property of their respective owners.

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# PROSPECTUS SUMMARY

This summary highlights information in this prospectus and is qualified in its entirety to the more detailed information and financial statements included elsewhere herein. This summary may not contain all the information that may be important to you. Before making an investment decision, you should read carefully the entire prospectus including the information under the Risk Factors section and our financial statements and related notes.

In this Prospectus, references to Innovus Pharmaceuticals, Inc., Innovus Pharma, FasTrack, the Company, we, us, or and words of similar import and meaning refer to Innovus Pharmaceuticals, Inc., the Registrant.

References to North Horizon, North Horizon, Inc. refer to the pre-transaction public shell.

In this report references to a major related party of the Company Apricus Biosciences, Inc (Nasdaq: APRI) (Apricus Bio), Bio-Quant, Inc. (Bio-Quant) and NexMed (U.S.A.), Inc., (NexMed) may be used interchangeably, but shall represent the same entity.

### **Our Business**

Innovus Pharmaceuticals, Inc. (the *Company*, *Innovus Pharma*, *FasTrack*, *we*, *us* and *our*) is focused on n revenue opportunities through the commercialization of its proprietary product pipeline, currently consisting of therapies aimed at pain relief and bleeding of the gums. Additionally, the Company is actively seeking to in-license and/or to acquire new and innovative pharmaceutical compounds that offer definable pathways to regulatory approval, partnering and commercialization.

Our business model is to create multiple opportunities for success while minimizing the risks associated with reliance on any single technology platform or product type, and to bridge the critical gap between promising new product candidates and product opportunities that are ready for commercialization. Consistent with our long-term strategy, we intend to consider various corporate development transactions to place our product candidates into larger organizations or with partners having existing commercialization, sales and marketing resources, and a need for innovative products. Such transactions could involve the sale, partnering or other monetization of particular product opportunities or businesses.

In parallel, as our business strategy advances and corresponding valuations are established, we plan to pursue new product opportunities and acquisitions with strong value enhancement potential. Our long-term goal is to improve our balance sheet and cash flow. This strategy may include debt financing and/or acquisitions of small revenue generating companies and products.

# **Our Proprietary Product and Technology Portfolios**

The lead product in our pipeline is Apeaz<sup>TM</sup>, a topical cream for pain relief. It is intended to deliver different ingredients to various layers of the skin and muscle, and optimize effect. The product had previously been sold in the U.S. and internationally, and had cumulative sales of up to \$500,000. However, all sales for the product were abandoned in 2008, when the U.S. distributor went out of business, and the previous owner of Apeaz<sup>TM</sup> decided to focus on another segment of its business. The Company needs approximately \$30,000 to repackage and relaunch the product in the U.S. and internationally.

In addition, we have Regia<sup>TM</sup>, which is a plant-derived, anti-microbial agent for reducing the bleeding of gums when used in OTC products such as mouthwash. The same active is currently included in a mouthwash commercialized in France. We have an issued US patent which expires in May 2028 and patent applications pending in selected international markets. Our intention is to out-license the patent portfolio for Regia<sup>TM</sup> to potential development partners.

In our portfolio of Rx products, we have a partial interest in the potential commercial value of PrevOnco<sup>TM</sup>, a Phase 2/3 second-line Orphan Drug therapy for patients with hepatocellular carcinoma or liver cancer.

Within our Rx portfolio is a development platform based on SSAO inhibitors. SSAO is known as vascular adhesion protein-1 or VAP-1, and is a dual function molecule with enzymatic and cell adhesion

activities. These inhibitors are designed to reduce inflammation by blocking the white blood cells and reducing the levels of inflammatory mediators.

### **Prior Transactions**

Innovus Pharma, formerly known as North Horizon, Inc., was incorporated under the laws of the State of Utah on January 15, 1959. It changed the corporate domicile to the State of Nevada in 2007. In December 2011, North Horizon changed its name to Innovus Pharmaceuticals, Inc., and subsequently entered into a combination transaction with FasTrack Pharmaceuticals, Inc., whereby FasTrack became wholly-owned subsidiary of North Horizon, Inc.

FasTrack was organized by shareholders of Bio-Quant, which was a Utah corporation founded in 2000 and operated as a contract research organization for the pharmaceutical industry. In late 2008, Bio-Quant decided to focus on its core business of pre-clinical testing services, and sold its pharmaceutical assets to FasTrack and Sorrento Pharmaceuticals, Inc. (Sorrento), which focused on the development of Rx and OTC products, respectively. The limited funding of both FasTrack and Sorrento severely limited their activities and operations. In March 2011, the shareholders of FasTrack and Sorrento decided to combine operations in an effort to better position the combined entity for new investors. Pursuant to an asset purchase agreement between the two companies. FasTrack acquired Sorrento s assets and liabilities.

# **Reverse Merger**

On December 7, 2011, the North Horizon completed a combination transaction with FasTrack Pharmaceuticals, Inc., a Delaware corporation, which became a wholly-owned subsidiary of North Horizon, Inc. (subsequently Innovus Pharma). FasTrack was a specialty pharmaceutical company with a development pipeline of Rx and OTC products. The combination caused the shareholders of FasTrack to have actual and effective operating control of the combined entity. The transaction has been accounted for as a reverse merger, whereby North Horizon is the legal acquirer and FasTrack is the legal acquiree and the accounting acquirer.

Immediately before the combination, North Horizon s issued and outstanding shares in the amount of 13,251,250 were subject to a reverse split on the basis of ten shares into one share (10:1) The reverse split was effective on December 6, 2011.

The following is a summary of the changes and actions that resulted from the closing of the Agreement.

Name Change: Innovus Pharmaceuticals, Inc.

Capitalization: 150,000,000 shares of common stock.

Directors: Vivian Liu, Henry Esber, Ph.D. and Ziad Mirza, M.D.,

Reverse Split: A reverse split on the basis of ten shares into one share (10:1) of the issued and

outstanding shares.

Our business address is 80 West Sierra Madre Blvd. #392, Sierra Madre, California 91024, telephone number 626-227-1630.

# **Our Plans and Business Model**

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Our business model is designed to create multiple opportunities for growth while minimizing the risks associated with reliance on any single technology platform or product type, and to bridge the critical gap between promising new product candidates and product opportunities that are ready for commercialization. Consistent with our long-term strategy, we intend to consider various corporate development transactions designed to place our product candidates into larger organizations or with partners having existing commercialization, sales and marketing resources, and a need for innovative products. Such transactions could involve the sale, partnering or other monetization of particular product opportunities or businesses.

In parallel, as our business strategy advances and corresponding valuations are established, we plan to pursue new product opportunities and acquisitions with strong value enhancement potential. Our long-term goal is to improve our balance sheet and cash flow. This strategy may include debt financing and/or acquisitions of small revenue generating companies and products.

# The Offering

### Selling stockholders

As of the date of the prospectus we have issued and outstanding 16,333,670 shares of common stock. Of those shares 9,959,168 are held by affiliates of the Company (approximately 60%).

The 150,580 shares being offered pursuant to this prospectus represent approximately less than one per cent of the total outstanding shares. The selling shareholders are not considered affiliates. They are listed under the caption Selling Stockholders section.

Shares of common stock offered by the Company None.

Trading Market Our shares are traded from time to time on the OTCBB under the symbol INNV.

Shares of common stock which may be sold by the selling stockholders 150,580 shares

### Use of proceeds

We will not receive any proceeds from the resale of shares offered by the selling stockholders. Any proceeds will be paid to the selling stockholders.

Risk factors The purchase of our common stock involves a high degree of risk as highlighted herein.

#### Plan of distribution

Our expectation is that the selling stockholders will sell their shares primarily through sales into the OTCBB market, made from time to time at prices the selling stockholders consider and deem to be appropriate and adequate. (See Plan of Distribution. )

# **Our Common Stock**

Currently we have authorized capitalization of 150,000,000 shares of common stock, par value of \$.001 per share and there are 16,333,670 shares issued and outstanding.

# **Summary Financial Information**

The December 7, 2011 combination between North Horizon and FasTrack was accounted for as a reverse acquisition and recapitalization with FasTrack being the acquirer. Accordingly the consolidated financial statements and the summary financial information set forth are in substance those of Fastrack as the accounting acquirer, with the assets and liabilities and the revenues and expenses of North Horizon being included, effective from the acquisition date. The historical financial statements for periods prior to the acquisition are those of FasTrack except the equity section earnings per share have been retroactively restated to reflect the acquisition.

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# **SUMMARY FINANCIAL INFORMATION**

The summary historical financial information presented as of December 31, 2011 is derived from audited financial statements of Innovus Pharmaceuticals, Inc, that are included elsewhere in this prospectus. The summary historical financial information presented as of December 31, 2010 is derived from the audited financial statements of FasTrack Pharmaceuticals, Inc., the accounting acquirer, that are included elsewhere in this prospectus. The summary historical financial information presented as of the three and six months ended June 30, 2012 are derived from the unaudited historical financial statements of Innovus Pharmaceuticals, Inc. included elsewhere in this prospectus. The summary historical financial information presented as of the three and six months ended June 30, 2011 are derived from the unaudited historical financial statements of FasTrack Pharmaceuticals, Inc., the accounting acquirer, that are included elsewhere in this prospectus.

# **Statement of Operations Data**

	months en	ded 012	For the thr months en June 30, 2 (unaudited	ded 011			For the six months en June 30, 24 (unaudited	ded 011	For the year ended December 31, 2011 (audited)	For the year ended December 31, 2010 (audited)	From October 31, 2008 (Inception) through June 30, 2012 (unaudited)
Revenue											
Total operating expenses (\$)	49,849		50,994		106,126		71,200		2,188,535	53,601	2,368,386
Net loss (\$)	(54,321	)	(55,724	)	(114,581	)	(80,250	)	(2,256,252)	(69,923)	(2,468,126)
Basic loss per share (\$)	(0.00	)	(0.00	)	(0.02	)	(0.01	)	(0.16)	(0.01)	
Weighted average number of shares outstanding (#)	13,764,64	18	14,722,07	77	7,593,514		14,609,76	64	13,785,487	13,681,876	

### **Balance Sheet Data**

	June 30, 2012	December 31, 2011	December 31, 2010
ASSETS			
Total Current Assets	\$ 105,726	\$ 25,014	\$ 1,650
Total Assets	\$ 105,726	\$ 25,014	\$ 1,650
LIABILITIES AND STOCKHOLDERS			
EQUITY (DEFICIT)			
Current Liabilities			
Total Current Liabilities	\$ 221,213	\$ 138,855	\$ 253,155
Contingency liability		\$ 28,926	\$ 28,926
Common stock	16,334	1,325	13,754

Additional paid-in-capital	2,733,183	2,606,331	228,912
Deficit accumulated during the development stage	(2,865,004)	(2,750,423)	(494,171)
Total stockholders equity (deficit)	(115,487)	(142,767)	(251,505)

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# **RISK FACTORS**

Our business endeavors and our common stock involve a high degree of risk. You should carefully consider the risks described below with all of the other information included in this Prospectus. An investment in our common stock involves significant risks, and should not be made by anyone who cannot afford to lose his or her entire investment. You should carefully consider the following risks together with all other information contained in this prospectus before deciding to invest in our common stock. If any of the following risks actually occur, they may materially harm our business and our financial condition and results of operations. In that event, the market price of our common stock could decline, and investors could lose part or all of their investment.

# **Risks Related to the Company**

# We continue to require external financing to fund our operations, which may not be available.

We will need a positive cash flow to fund our ongoing operations, including the development of our products under development and the annual costs to remain a public company, including legal, audit and listing fees. To date, we have been dependent on loans from our current and former management and directors, and from Apricus Bio, a related party. We cannot continue to depend on these sources to continue our operations in the long term.

Given our current lack of cash resources, we will not be able to implement our growth strategy unless we raise significant capital, enter into licensing and commercialization agreements, or partnering agreements. If we are unable to accomplish these objectives, we would be unable to advance certain programs and may have to curtail our operations.

Given the current market conditions, there is no assurance that we will be successful.

Based on the factors described above there is substantial doubt as to the our ability to continue as a going concern, as further discussed in Footnote 2 Going Concern to the Consolidated Financial Statements.

### We will continue to incur operating losses.

We have not marketed or generated sales revenues from our product candidates under development. We have never been profitable and have incurred an accumulated deficit of approximately \$2,750,000 since our inception through December 31, 2011. Our ability to generate revenues and to achieve profitability and positive cash flow will depend on the successful licensing and commercialization of our product candidates currently approved or in human clinical trials and those earlier stage products and technology under development.

Our ability to become profitable will depend, among other things, on our (1) raising sufficient capital to implement our growth strategy, (2) obtaining of regulatory approvals of our proposed product candidates, (3) success in licensing, manufacturing, distributing and marketing our proposed product candidates, if approved, and (4) increasing profitability through acquisitions and growth and development of our operations. If we are unable to accomplish these objectives, we may be unable to achieve profitability and would need to raise additional capital to sustain and continue our operations.

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# We may have liability for shares of our common stock issued in the reverse merger.

Questions arose as to whether as of the record date the FasTrack shareholders received adequate information regarding the combination and merger with North Horizon. The FasTrack shareholders reside in thirteen states and commonwealths. The securities statutes of these jurisdictions have exemptions for an exchange or for a transaction that is termed an isolated transaction. We made a rescission offer and provided detailed information to FasTrack shareholders. The offer expired and no FasTrack shareholder accepted the offer. Liability may exist and will lapse when the applicable statute of limitation runs and expires. The FasTrack shareholders reside in different jurisdictions and the statutes of limitations in these jurisdictions have different terms, the longest being four years. Until a claim is made there will be no impact on the Company. We are unable to predict if any shareholder will make a claim and if pursued what any outcome may be.

# If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully operate our business.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and scientific personnel and on our ability to develop and maintain important relationships with healthcare providers, clinicians and scientists. We are highly dependent upon our management, particularly Vivian Liu, our President and Chief Executive Officer. Although we have an employment agreement with Ms. Liu, these types of agreements are generally terminable at will at any time, and, therefore, we may not be able to retain her services as expected. The loss of the services of Ms. Liu could delay or prevent us from obtaining financing and implementing our business strategy. Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We may need to hire additional personnel as we expand our commercial activities. We may not be able to attract and retain qualified personnel on acceptable terms.

Our ability to maintain, expand or renew our business and to get business from new clients, particularly in the drug development sector, also depends on our ability to subcontract and retain scientific staff with the skills and expertise necessary to keep pace with continuing changes in drug development technologies.

# We do not have our own proprietary technology and will have to license technology for our own product development programs.

To successfully develop new products based on generic drugs currently on the market, we will need to license in a delivery technology, which would enable us to differentiate our product from its generic counterparts. We may not be able to obtain the right to a suitable technology to develop our targeted drug candidates.

Consummation of licensing arrangements is subject to the negotiation of complex contractual relationships and we may be unable to negotiate such agreements timely, if at all, or on acceptable terms.

# We face significant competition and have limited resources compared to our competitors.

We are engaged in a highly competitive industry. We can expect competition from numerous companies, including large international enterprises, and others entering the market for products similar to ours. Most of these companies have greater research and development, manufacturing, patent, legal, marketing, financial, technological, personnel and managerial resources. Acquisitions of competing companies by large pharmaceutical or healthcare companies could further enhance such competitors financial, marketing and other resources. Competitors may complete clinical trials, obtain regulatory approvals and commence commercial sales of their products before we could enjoy a significant competitive advantage. Products developed by our competitors may be more effective than our product candidates.

We currently have no sales force or marketing organization and will need, but may not be able, to attract marketing partners or afford qualified or experienced marketing and sales personnel for our product candidates under development.

We have no internal sales and marketing capabilities. In order to market our OTC product candidate directly to customers, we will need to build a sales and marketing infrastructure and/or attract marketing partners that will need to spend significant funds to inform potential customers, including third-party distributors, of the distinctive characteristics and benefits of our product candidates. Our operating results and long term success will depend, among other things, on our ability to establish (1) successful arrangements with domestic and additional international distributors and marketing partners and (2) if we cannot find such partners or choose to market and sell the product directly to customers, an effective internal marketing and sales organization. Consummation of partnering arrangements is subject to the negotiation of complex contractual relationships, and we may not be able to negotiate such agreements on a timely basis, if at all, or on terms acceptable to us. If we enter into third party arrangements, our revenues would be lower as we would share the revenues with our licensing, commercialization and development partners. If we are unable to launch a drug, we may realize little or no revenue from sales in the OTC market.

# We are an emerging growth company and qualify for reduced reporting requirements so long as we remain an emerging growth company.

The recently enacted JOBS Act reduces certain disclosure requirements for emerging growth companies thereby decreasing related regulatory compliance costs. We qualify as an emerging growth company as of the date of his offering and may continue to qualify as an emerging growth company for up to five years.

For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include (1) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and (iii) exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. However, we would cease to qualify as an emerging growth company if:

We have annual gross revenues of \$1.0 billion or more in a fiscal year;

We have, during the previous three-year period issued more than \$1.0 billion in non-convertible debt; or We become a large accelerated filer , defined by the SEC as a company with a world-wide public float of our common stock of \$700 million or more.

Upon the occurrence of any of the above, we would not be able to take advantage of the reduced regulatory requirements and any associated cost savings.

# Pre-clinical and clinical trials are inherently unpredictable. If we or our partners do not successfully conduct these trials or gain regulatory approval, we or our partners may be unable to market our product candidates.

Through pre-clinical studies and clinical trials, our product candidates must be demonstrated to be safe and effective for the indicated uses. Results from pre-clinical studies and early clinical trials may not be indicative of, or allow for prediction of results in later-stage testing. Many of the pre-clinical studies that we have conducted are in animals with models of human disease states. Although these tests are widely used as screening mechanisms for drug candidates before being advanced to human clinical studies, results in animal studies are less reliable predictors of safety and efficacy than results of human clinical studies. Future clinical trials may not demonstrate the safety and effectiveness of our product candidates or may not result in regulatory approval to market our product candidates. Commercial sales in the United States of our product candidates cannot begin until final FDA approval is received. The failure of the FDA to approve our product candidates for commercial sales will have a material adverse effect on our prospects and could have a negative effect on the Company s stock price.

# Patents and intellectual property rights are important to us but could be challenged.

Proprietary protection for our pharmaceutical products and products under development is of material importance to our business in the U.S. and most other countries. We have sought and will continue to seek proprietary protection for our product candidates to attempt to prevent others from commercializing equivalent products in substantially less time and at substantially lower expense. Our success may depend on our ability to (1) obtain effective patent protection within the U.S. and internationally for our proprietary technologies and products, (2) defend patents we own, (3) preserve our trade secrets, and (4) operate without infringing upon the proprietary rights of others. In

We are an emerging growth company and qualify for reduced reporting requirements so long as we remain an en

addition, we have agreed to indemnify our partners for certain liabilities with respect to the defense, protection and/or validity of our patents and would also be required to incur costs or forego revenue if it is necessary for our partners to acquire third party patent licenses in order for them to exercise the licenses acquired from us.

While we have obtained patents and have many patent applications pending, the extent of effective patent protection in the U.S. and other countries is highly uncertain and involves complex legal and factual

questions. No consistent policy addresses the breadth of claims allowed in or the degree of protection afforded under patents of medical and pharmaceutical companies. Patents we currently own or may obtain might not be sufficiently broad enough to protect us against competitors with similar technology. Any of our patents could be invalidated or circumvented.

While we believe that our patents would prevail in any potential litigation, the holders of competing patents could determine to commence a lawsuit against us and even prevail in any such lawsuit.

## We are dependent upon third party contract research organizations ( CROs ).

We currently do not have our own research and development infrastructure. To-date, our studies have been conducted by NexMed, a subsidiary of Apricus (a related party), for a fee. Assuming we successfully raise sufficient capital to implement our product development programs, we intend to contract the studies to third party CROs. If the CRO fails to conduct the contracted studies on a timely and satisfactory basis, we would experience and encounter costs and delays in identifying new CROs.

# We are dependent upon third party manufacturers for chemical manufacturing supplies.

We are dependent on third party chemical manufacturers. Any products must be supplied on a timely basis and at satisfactory quality levels. If our validated third party chemical manufacturers fail to produce quality products on time and in sufficient quantities, our results would suffer, as we would encounter costs and delays in validating new third party suppliers.

# We may be subject to potential product liability and other claims, creating risks and expense.

We are also exposed to potential product liability risks inherent in the development, testing, manufacturing, marketing and sale of human therapeutic products. Product liability insurance for the pharmaceutical industry is extremely expensive, difficult to obtain and may not be available on acceptable terms, if at all. We may need to acquire such insurance coverage prior to the commercial introduction of our product candidates. If we obtain coverage, we have no guarantee that the coverage limits of such insurance policies will be adequate. A successful claim against us if we are uninsured, or which is in excess of our insurance coverage, if any, could have a material adverse effect upon us and on our financial condition.

# **Industry Risks**

### We are vulnerable to volatile stock market conditions.

The market prices for securities of biopharmaceutical and biotechnology companies, including ours, have been highly volatile. The market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. In addition, future announcements, such as the results of testing and clinical trials, the status of our relationships with third-party collaborators, technological innovations or new therapeutic products, governmental regulation, developments in patent or other proprietary rights, litigation or public concern as to the safety of products developed by us or others and general market conditions, concerning us, our competitors or other biopharmaceutical companies, may have a significant effect on the market price of our common

stock.

Instability and volatility in the financial markets and the global economic recession are likely to have a negative impact on our ability to raise necessary funds and on our business, financial condition, results of operations and cash flows.

During the past several years, there has been substantial volatility and a decline in financial markets due in part to the lethargic global economic environment. In addition, there has been substantial uncertainty in the capital markets and access to financing is uncertain. These conditions are likely to have an adverse effect on our industry, licensing partners, and business, including our financial condition, results of operations and cash flows.

To the extent that we do not generate sufficient cash from operations, we may need to raise capital through equity sales and/or incur indebtedness, if available, to finance operations. However, recent turmoil in the capital markets and the potential impact on the liquidity of major financial institutions may have an

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adverse effect on our ability to fund our business strategy through sales of capital stock or through borrowings, under either existing or newly created instruments in the public or private markets on terms that we believe to be reasonable, if at all.

# Changes in trends in the pharmaceutical and biotechnology industries, including difficult market conditions, could adversely affect our operating results.

The biotechnology, pharmaceutical and medical device industries generally and drug discovery and development more specifically are subject to increasingly rapid technological changes. Our competitors and others might develop technologies or products that are more effective or commercially attractive than our current or future technologies or products, or that render our technologies or products less competitive or obsolete. If competitors introduce superior technologies or products and we cannot make enhancements to our technologies or products to remain competitive, our competitive position, and in turn our business, revenue and financial condition, would be materially and adversely affected.

# We and any potential licensees are subject to numerous and complex government regulations which could result in delay and expense.

Governmental authorities in the U.S. and other countries heavily regulate the testing, manufacture, labeling, distribution, advertising and marketing of our proposed product candidates. Before any products we develop are marketed, FDA and comparable foreign agency approval must be obtained through an extensive clinical study and approval process.

The failure to obtain requisite governmental approvals for our product candidates under development in a timely manner or at all would delay or preclude us and our licensees from marketing our product candidates or limit the commercial use of our product candidates, which could adversely affect our business, financial condition and results of operations.

Any failure on our part to comply with applicable regulations could result in the termination of on-going research, discovery and development activities or the disqualification of data for submission to regulatory authorities.

Because we intend that our product candidates will be sold and marketed outside the U.S., we and/or our potential licensees will be subject to foreign regulatory requirements governing the conduct of clinical trials, product licensing, pricing and reimbursements. These requirements vary widely from country to country. The failure to meet each foreign country s requirements could delay the introduction of our proposed product candidates in the respective foreign country and limit our revenues from sales of our proposed product candidates in foreign markets.

Successful commercialization of our product candidates may depend on the availability of reimbursement to the consumer from third-party healthcare payers, such as government and private insurance plans. Even if one or more products are successfully brought to market, reimbursement to consumers may not be available or sufficient to allow the realization of an appropriate return on our investment in product development or to sell our product candidates on a competitive basis. In addition, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to governmental controls. In the U.S., federal and state agencies have proposed similar governmental control and the U.S. Congress has recently adopted regulatory reforms that affect companies engaged in the healthcare industry. Pricing constraints on our product candidates in foreign markets and possibly in the U.S. could adversely

affect our business and limit our revenues.

# We face uncertainty related to healthcare reform, pricing and reimbursement which could reduce our revenue potential.

In 2009 and 2010, the U.S. Congress adopted legislation regarding health insurance, which has been signed into law. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of private payers

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and government programs, such as Medicare, Medicaid and State Children s Health Insurance Program, creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes.

Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, biopharmaceuticals, medical devices, or our product candidates. If reimbursement for our approved product candidates, if any, is substantially less than we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

Recently, there have been efforts in the U.S. Congress to defund the health insurance program described above. As a result of the political uncertainty surrounding the implementation of the health care legislation, it is unclear as to what laws, regulations, procedures and funding will be put into place in the near future. Such uncertainty may impact the reimbursement for certain prescribed drugs, biopharmaceuticals, medical devices, or our product candidates. As described above, if reimbursement for our approved product candidates, if any, is substantially less than we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

Sales of our product candidates, if approved for commercialization, will depend in part on the availability of coverage and reimbursement from third-party payers such as government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other health care related organizations. Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation affecting coverage and reimbursement policies, which are designed to contain or reduce the cost of health care. Further federal and state proposals and healthcare reforms are likely which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. There may be future changes that result in reductions in current coverage and reimbursement levels for our products, if commercialized, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations.

Adoption of our product candidates, if approved, by the medical community may be limited if third-party payers will not offer coverage. Cost control initiatives may decrease coverage and payment levels for drugs, which in turn would negatively affect the price that we will be able to charge. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payers to any drug candidate we have in development. Any denial of private or government payer coverage or inadequate reimbursement for procedures performed using our drug candidates, if commercialized, could harm our business and reduce our revenue.

# Risks Related to Owning our Common Stock

# Our stock could become ineligible to be listed on the OTCBB.

Currently, our common stock trades on the OTCBB. We have been informed of a three-strike rule. In the past two years we filed one periodic report late. If we file a report untimely twice again any time before August 2013 we most likely will not have our shares quoted on the OTCBB. It is possible that we could be out of compliance in the future. If we fail to maintain compliance with any listing requirements, we could be ineligible for the OTCBB, and have to trade our stock on the Pink Sheets.

We have provided Ms. Liu with anti-dilution protection with respect to her ownership in the Company, which will result in our issuing Ms. Liu additional shares over the next two years.

We face uncertainty related to healthcare reform, pricing and reimbursementwhich could reduce our reveale poten

Pursuant to the employment agreement we provided Ms. Liu, we agreed to grant Ms. Liu 6% of our outstanding common stock in the form of restricted stock that vested over a period of 36 months. The employment agreement states that if additional shares of stock are issued during the vesting period of 36 months since the grant date, Ms. Liu will be issued additional shares so that she would retain 2%, 4% and 6% ownership of the Company at December 31, 2011, 2012 and 2013, respectively. No additional shares were issued through June 30, 2012 as Ms. Liu s ownership as of June 30, 2012 exceeded 2%.

There are restrictions on resale of the Company s Common Stock by many of our shareholders and there is no assurance that when these shares become available to sale into the market that these shares will be assimilated without a substantial decline in the market price of our shares of common stock.

The restrictions on resale may be removed through the provisions of Rule 144 under the Securities Act. We were a shell issuer until December 2011 (when the Form 10 information was filed with the SEC), Rule 144 is not available until December 2012 at the earliest. When our shareholders are able to rely on the provisions of Rule 144 their sales into the market may adversely affect the market price of our shares.

### There has been a limited trading market for our Common Stock to date.

Currently, our common stock is available for quotation on the OTCBB under the symbol INNV. However, to date, there has been virtually no trading activity in our common stock. It is anticipated that there will continue to be a limited trading market for the common stock in the near future. The lack of an active market may impair your ability to sell your Common Stock at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital by selling shares of common stock and may impair our ability to acquire other companies by using common stock as consideration.

# Our stock is considered a penny stock under SEC regulations and may have limited market liquidity.

Our stock is considered a penny stock under regulations of the Securities and Exchange Commission and is subject to rules that impose additional sales practice requirements on broker-dealers who sell our securities. The additional burdens imposed upon broker-dealers by these requirements may discourage broker-dealers from effecting transactions in our common stock, which may severely limit the market liquidity of the common stock and the ability of our shareholders to sell our securities in the secondary market.

# As an emerging growth company, (as described earlier in this document) we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. Accordingly, we are eligible to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies. Additionally Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to take advantage of the benefits of this extended transition period and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

As long as we are an emerging growth company, we cannot predict if investors will find our common stock less attractive because we may not rely on exemptions provided by the JOBS Act. If some investors find our common

There are restrictions on resale of the Company s Common Stock by many of our shareholders and there as no ass

stock less attractive, there may be a less active trading market for our common stock and our stock price may be more volatile.

# We do not expect to pay dividends on our common stock in the foreseeable future.

Although our stockholders may receive dividends if, as and when declared by our board of directors, we do not intend to declare dividends on our common stock in the foreseeable future. Therefore, investors may not purchase our common stock if they need immediate or future income by way of dividends from their investment.

# We may issue additional shares of our capital stock that could dilute the value of your shares of common stock.

We are authorized to issue 150,000,000 shares of our common stock. In light of our possible future need for additional financing, we may issue additional shares of common stock below current market prices that could dilute the earnings per share and book value of our shares of our common stock. These issuances would dilute existing stockholders and could depress the value of our common stock.

In addition to provisions providing for proportionate adjustments in the event of stock splits, stock dividends, reverse stock splits and similar events, outstanding warrants representing the right to acquire shares of common stock may cause an adjustment of the exercise or conversion price if we issue shares of common stock at prices lower than the then exercise or conversion price or the then prevailing market price. This means that if we need to raise equity financing at a time when the market price for our common stock is lower than the exercise or conversion price, or if we need to provide a new equity investor with a discount from the then prevailing market price, then the exercise price will be reduced and the dilution to stockholders increased.

# Due to our limited public float, a large influx of free and tradable shares could negatively impact our stock price.

We have limited public float in the trading market for our shares of common stock. Previously the Company was designated as a shell company as defined by the SEC. Rule 144 states that the provisions of Rule 144 are unavailable to shareholders of a shell company until 12 months after a former shell company files information that includes disclosures similar to information provided in a Form 10 filed with the SEC. On December 12, 2011, we filed a report on Form 8-K, which we believe included disclosures that would be included in a Form 10. Thus, on December 12, 2012, the provisions of Rule 144 should become available to shareholders of the Company.

Shares held by Apricus Bio and others holding large positions influence the public float. These parties investment objectives may differ from other shareholders. If large shareholders decide to sell all or part of their shares, the market price of our shares may decrease significantly.

# DILUTION

We are not offering or selling any of the shares of common stock in this offering. All of the offered shares are held by the selling stockholder and accordingly, no dilution will result from the sale of the shares.

# MARKET FOR OUR COMMON STOCK

Our common stock is presently trading on the OTCBB under the symbol INNV, although there has not been an active trading market for our shares. Accordingly we are not including a history of reported trades in the public market. The most recent reported trade was on August 6, 2012 at \$2.25 per share.

Inclusion on the OTCBB permits price quotations for our shares to be published by that service. We cannot make any assurance that an active trading market for our shares will develop in the future or, that if such a market does develop, that it can be sustained. Any secondary trading of our shares may be subject to certain state imposed restrictions. We have no plans regarding the development of a trading market in any of our shares of common stock.

The ability of individual stockholders to trade theirs shares in a particular state may be subject to various rules and regulations of that state. A number of states require that an issuer's securities be registered in their state or appropriately exempted from registration before the securities are permitted to trade in that state. Presently, we have no plans to register our securities in any particular state.

# **Penny Stock Rule**

It is unlikely that our securities will be listed on any national or regional exchange or The Nasdaq Stock Market in the foreseeable future. Most likely our shares will be subject to the provisions of Section 15g-9 of the Exchange Act commonly referred to as the penny stock rule. Rule 15g-9 sets forth certain requirements for broker-dealer transactions in penny stocks and Rule 15g-9(d)(1) incorporate the definition of penny stock as that used in Rule 3a51-1 of the Exchange Act.

The SEC defines a penny stock to be any equity security that has a market price less than \$5.00 per share, subject to certain exceptions. Rule 3a5l-l provides that any equity security be considered to be a penny stock unless that security is:

Registered and traded on a national securities exchange meeting specified criteria set by the SEC;

Authorized for quotation on The Nasdaq Stock market;

Issued by a registered investment company;

Excluded from the definition on the basis of price (at least \$5.00 per share) or the issuer's net tangible assets; or Exempted from the definition by the SEC.

Broker-dealers who sell penny stocks to persons other than established customers and accredited investors are subject to additional sales practice requirements. An accredited investor is generally defined as a person with assets in excess of \$1,000,000 not including the value of the personal residence unless the equity in the residence has a negative value which is then deducted from the net assets or annual income exceeding \$200,000 or \$300,000 together with their spouse.

For transactions covered by these rules, broker-dealers must make a special suitability determination for the purchase of such securities and must receive the purchaser's written consent to the transaction prior to the purchase.

Additionally, for any transaction involving a penny stock, unless exempt, the rules require the delivery prior to the transaction of a risk disclosure document relating to the penny stock market. A broker-dealer also must disclose the commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements must be sent to clients disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. Consequently these rules may restrict and impair the ability of broker-dealers to trade and maintain a market in our common stock and may affect the ability of stockholders to sell their shares.

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Penny Stock Rule 27

These requirements may be considered cumbersome by broker-dealers and could impact the willingness of a particular broker-dealer to make a market in our shares, or they could affect the value at which our shares trade. Classification of the shares as penny stocks increases the risk of any investment in our shares.

### **Rule 144**

A total of 16,014,798 shares of the 16,333,670 shares of common stock presently outstanding and not being registered for resale under this prospectus are deemed to be restricted securities as defined by Rule 144 under the Securities Act. Rule 144 is the common means used by a stockholder to resell restricted securities and for affiliates to sell their securities, either restricted or non-restricted control shares. The SEC amended Rule 144 effective February 15, 2008.

Under the amended Rule 144, an affiliate of a company which filed periodic reports under the Exchange Act who has held their shares for more than six months, may sell in any three month period the number of shares that does not exceed the greater of:

The average weekly trading volume in the common stock, as reported through the automated quotation system of a registered securities association during the four calendar weeks preceding such sale, or 1% of the shares then issued and outstanding.

Sales by affiliates under Rule 144 are also subject to certain requirements as to the manner of sale, filing appropriate and proper notice and the availability of current public information about the issuer of the securities.

Sales by a non-affiliate stockholder of a reporting company who has held the shares for more than six months, may make unlimited resales under Rule 144 provided only that the issuer has available current public information about itself. After a one-year holding period, a non-affiliate may make unlimited sales with no other requirements or limitations.

An exception to the availability of the provisions of amended Rule 144 is that Rule 144 is not available for either a reporting or a non-reporting shell company, unless the company: has ceased to be a shell company; is subject to the Exchange Act reporting obligations; has filed all required Exchange Act reports during the preceding twelve months; and at least one year has elapsed from the time the company filed with the SEC current Form 10 type information reflecting the status of the entity that is not a shell company.

We cannot predict the effect any future sales under Rule 144 may have on the market price of our common stock, but such sales may have a substantial depressing effect on any such market price.

# **DIVIDEND POLICY**

We have never declared cash dividends on our common stock. We do not anticipate paying any dividends on our common stock in the future.

### THE OFFERING

Commencing on the date of this prospectus the selling stockholders propose to offer shares of common stock in the over-the-counter market or otherwise, at market prices prevailing at the time of sale, at prices related to the prevailing market price, or at negotiated prices.

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Our shares are presently quoted on the OTCBB. No assurance can be made that a more active market for our shares will develop.

# **PLAN OF DISTRIBUTION**

The selling stockholders identified in this prospectus may offer and sell up to 150,580 shares of our common stock. The selling stockholders may sell all or a portion of the shares of common stock through public or private transaction at prevailing market prices or at privately negotiated prices. As used in this prospectus—selling stockholders—include pledges, transferees or other successors-in-interest selling shares received from the selling stockholders, as pledges, assignees, borrowers or in connection with other non-sale-related transfers after the date of this prospectus. This prospectus may also be used by transferees of

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the selling stockholders, including broker-dealers or other transferees who borrow or purchase the shares to settle or close out short sales of shares of common stock. The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale or non-sale related transfer. We will not receive any of the proceeds from sales by the selling stockholders.

We expect that the selling stockholders will sell their shares primarily through the over-the-counter market made from time-to-time at prevailing market prices. The selling stockholders may sell from time to time in one or more transactions at or on any stock exchange, market or trading facility on which shares are traded in the future or in private transactions. Sales may be made a fixed or negotiated prices, and may be effected by means of one or more of the following transactions which may involve cross or block transactions: (1) ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers; (2) block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction; (3) purchases by a broker-dealer as principal and resale by the broker-dealer for its account; (4) an exchange distribution in accordance with the rules of the applicable exchange; (5) privately negotiated transactions; (6) settlement of short sales; (7) transactions in which broker-dealers may agree with the selling stockholder to sell a specified number of shares at a stipulated price per share; (8) through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; or (9) a combination of any of the above or any other method permitted pursuant to applicable law.

The selling stockholders may sell shares under available exemptions under the Securities Act, such as Rule 144, if available, rather than under this prospectus. The selling stockholder will have the sole discretion not to accept any purchase offer or make any sale of his shares if he deems the purchase price unsatisfactory at a particular time. To the extent required this prospectus may be amended and supplemented from time to time to describe a specific plan of distribution, if appropriate or required.

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders or, if any broker-dealer acts as agent for the purchase of shares from the purchaser, in amounts to be negotiated. Selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

In connection with sales of common stock or interests therein the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales, puts and calls or other transactions in our securities or derivatives of our securities and may sell and deliver shares in connection with these transactions.

Selling stockholders and broker-dealers or agents involved in an arrangement to sell any of the offered shares may, under certain circumstances, be deemed to be underwriters within the meaning of the Securities Act. Any profit on such sales and any discount, commission, concession or other compensation received by any such underwriter, broker-dealer or agent may be deemed an underwriting discount and commission under the Exchange Act. The selling stockholders have not informed us that they have any agreement or understanding, directly or indirectly, with any persons to distribute the common stock. If either of the selling stockholders should notify us that they have a material arrangement with a broker-dealer for the resale of his shares, we may be required to amend the registration statement of which this prospectus is a part, and file a prospectus supplement to describe the agreement between a selling stockholder and broker-dealer or agent.

We have agreed to pay all fees and expenses incurred by us incident to the registration of the common stock, including SEC filing fees. The selling stockholders will be responsible for all costs and expenses in connection with the sale of their shares, including brokerage commissions or dealer discounts. We will indemnify the selling stockholders against

certain losses, claims, damages and liabilities including liabilities under the Securities Act.

Once sold under the registration statement of which this prospectus is a part, the shares of common stock will be freely tradeable in the hands of persons other than our affiliates.

The selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder which provisions may limit the time of purchases and sales of common stock. The

foregoing may affect the marketability of such securities. To comply with the securities laws of certain jurisdiction, if applicable, the common stock will be offered or sold in such jurisdictions only through registered or licensed brokers or dealers.

The selling stockholders and other persons participating in the sale or distribution of the shares offered hereby, will be subject to applicable provisions of the Exchange Ace and rules and regulations promulgated thereunder, including without limitation Regulation M. With certain exceptions Regulation M restricts certain activities of, and limits the time of purchases and sales of any of the shares by the selling stockholders, affiliated purchasers and any broker-dealer or other person who participates in the sale or distribution. Under Regulation M these persons are precluded from bidding for or purchasing or attempting to induce any person to bid for or purchase any security subject to the distribution until the distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of these limitations may affect the marketability of the shares offered by this prospectus. The selling stockholders are not broker-dealers or affiliates of any broker-dealer.

# SELLING STOCKHOLDERS

We are registering the shares of our common stock offered for resale pursuant to this prospectus to afford the selling stockholders the opportunity to sell their shares in a public transaction. The selling stockholders are offering hereby a total of 150,580 shares of our common stock. The following table provides information regarding the beneficial ownership of our common stock being offered for resale by the selling stockholders. Each selling stocker's percentage of ownership shown below is based on 16,333,670 shares of common stock issued and outstanding as of the date of this prospectus. The table includes the number of shares owned beneficially by each selling stockholder, the number of shares which may be offered for resale pursuant to this prospectus and the number of shares to be owned beneficially by each selling stockholder after the offering. The table has been prepared based on the assumption that all the shares of common stock offered under this prospectus will be sold. The selling stockholders are not affiliates of the Company. The selling stockholders may retain all or part of the shares they own. No prediction can be made of the number of shares the will be held by the selling stockholders upon termination of this offering.

Beneficial Ownership Name	Number of shares owned	Number of shares being registered	Number of shares owned after offering	Percentage after offering
Keith Cannon	162,563	134,000	28,563	1.0
Jibrayil Yusuf	164,909	16,580	148,329	1.0

### CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2012. This table should be read in conjunction with the financial statements and the notes thereto included elsewhere in this prospectus.

June 30, 2012 (unaudited)

150,000,000 shares authorized, par value \$0.001 per

share:

16,333,670 shares issued and outstanding

Common Stock

CAPITALIZATION 32

Additional paid in capital \$2,733,183

Deficit accumulated during development stage \$(2,865,004)

Total stockholders deficit \$(115,487)

# **LEGAL PROCEEDINGS**

As of the date of this prospectus we are not aware of any material claims, lawsuits, disputes with third parties or regulatory proceedings that would have any material affect on our company.

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# **JOBS ACT**

The JOBS Act provides that as long as a company qualifies as an emerging growth company it will, among other things:

be exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act reporting that its independent registered public accounting firm provide an attestation report on the effectiveness of its internal control over financial reporting;

be exempt from the say on pay and say on golden parachute advisory requirements of the Dodd-Frank Wall Street Reform and Customer Protection Act (the Dodd-Frank Act ), and certain disclosure requirements of the Dodd-Frank Act relating to compensation of its chief executive officer and be permitted to omit the detailed compensation discussion and analysis from proxy statements and reports filed under the Securities Exchange Act of 1934; and instead provide a reduced level of disclosure concerning executive compensation and be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor's report on the financial statements.

It should be noted that notwithstanding our status as an emerging growth company, we would be eligible for these exemptions as a result of our status as a smaller reporting company as defined in the Securities Exchange Act of 1934.

Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to take advantage of the benefits of this extended transition period and, therefore, will be subject to the same, new or revised accounting standards as other public companies that are not emerging growth companies.

# **BUSINESS**

Innovus Pharmaceuticals, Inc. (the *Company*, *Innovus Pharma*, *FasTrack*, *we*, *us* and *our*) is focused on new revenue opportunities through the commercialization of its proprietary product pipeline, currently consisting of therapies aimed at pain relief and bleeding of the gums. Additionally, the Company is actively seeking to in-license and/or acquire new and innovative pharmaceutical compounds that offer definable pathways to regulatory approval, partnering and commercialization.

Our business model is designed to create multiple opportunities for success while minimizing the risks associated with reliance on any single technology platform or product type, and to bridge the critical gap between promising new product candidates and product opportunities that are ready for commercialization. Consistent with our long-term strategy, we intend to consider various corporate development transactions designed to place our product candidates into larger organizations or with partners having existing commercialization, sales and marketing resources, and a need for innovative products. Such transactions could involve the sale, partnering or other monetization of particular product opportunities or businesses.

In parallel, as our business strategy advances and corresponding valuations are established, we plan to pursue new product opportunities and acquisitions with strong value enhancement potential. Our long-term goal is to improve our balance sheet and cash flow. This strategy may include debt financing and/or acquisitions of small revenue generating companies and products.

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# **Our Proprietary Product and Technology Portfolios**

The lead product in our pipeline is Apeaz<sup>TM</sup>, a topical cream that has been developed for pain relief. It is intended to deliver different ingredients to various layers of the skin and muscle, and optimize effect. The product had previously been sold in the U.S. and internationally, and had sales of approximately \$500,000. However, all sales for the product were abandoned in 2008, when the U.S. distributor went out of business, and the previous owner of Apeaz<sup>TM</sup> decided to focus on another segment of its business. The Company needs approximately \$30,000 to repackage and relaunch the product in the U.S. and internationally.

In addition, we have Regia<sup>TM</sup>, which is a plant-derived, anti-microbial agent for reducing the bleeding of gums when used in OTC products such as mouthwash. The same active is currently included in a mouthwash commercialized in France. We have an issued US patent which expires in May 2028 and patent applications pending in selected international markets. Our intention is to out-license the patent portfolio for Regia<sup>TM</sup> to potential development partners.

In our portfolio of Rx products, we have a partial interest in the potential commercial value of PrevOnco<sup>TM</sup>, a Phase 2/3 second-line Orphan Drug therapy for patients with hepatocellular carcinoma or liver cancer. PrevOnco<sup>TM</sup> is based on lansoprazole, a drug widely used to treat gastro-esophageal reflux disease. Preclinical animal data have shown the drug to also be effective in shrinking the tumors commonly associated with liver cancer. In 2010, FasTrack sold the development rights of the product to NexMed Holdings, Inc., ( *NexMed* ) a wholly-owned subsidiary of Apricus Biosciences, Inc. (Nasdaq: APRI) ( *Apricus Bio* ). In exchange, we are entitled to receive up to 50% of the net commercial value of the product in the event Apricus Bio successfully licenses the product to a commercialization partner. The potential for any returns on PrevOnco<sup>TM</sup> is completely dependent on Apricus Bio s efforts. Apricus Bio completely controls the future and progress of the PrevOnco<sup>TM</sup> program. There is no assurance that Apricus Bio will continue to develop it, or be successful in its development or licensing efforts.

When we have sufficient resources, we intend to explore and pursue new product opportunities based on drugs with expired or near-expired patents. Our strategy is to follow the 505(b)(2) regulatory approval pathway, which typically has a shorter development cycle with less pre-clinical and clinical studies required by the regulatory agencies. In June 2011, we conducted feasibility studies on two active drug ingredients identified by us. One study, completed in September 2011, focused on a new minoxidil formulation for treating hair loss. Minoxidil is the active ingredient in Rogaine®, a widely marketed topical product for treating male and female hair loss. The study results showed that our proprietary formulation significantly enabled the absorption of minoxidil into the human cadaver skin model.

Within our Rx portfolio is a development platform based on SSAO inhibitors. SSAO is known as vascular adhesion protein-1 or VAP-1, and is a dual function molecule with enzymatic and cell adhesion activities. These inhibitors are designed to reduce inflammation by blocking the white blood cells and reducing the levels of inflammatory mediators. A prior owner had developed a treatment for Lupus based on the SSAO platform, but that product failed in late-stage clinical studies. In 2009, FasTrack acquired the SSAO patent portfolio because of the possibility that the SSAO platform had potential for other developers to identify the right medical indication. Because the SSAO platform has unproven safety and efficacy profiles, to develop a product based on this platform would require significant resources and longer development time. We do not have these resources presently and no assurance can be given that even if proper resources were available, we would seek to develop or if development were pursued, a successful SSAO platform would be accomplished. To facilitate the SSAO development we may seek a partnership relationship.

# **Prior Transactions**

Innovus Pharma, formerly known as North Horizon, Inc., was incorporated under the laws of the State of Utah on January 15, 1959. It changed the corporate domicile to the State of Nevada in 2007. Initially, North Horizon had authorized capital of 100,000,000 shares of common stock, par value of \$.001 per share. Years ago it sold 100,000 shares of common stock to the public. It entered the cosmetic business, but this venture was unsuccessful. Other ventures ensued, but none were successful. For the past several years, there were no active business ventures, however, the management maintained North Horizon as a corporate entity and filed requisite reports with the U.S. Securities and Exchange Commission. Innovus Pharma has authorized capital of 150,000,000 shares of common stock, par value of \$.001 per share.

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In October 2011, North Horizon changed its name to Innovus Pharmaceuticals, Inc., and subsequently consummated a combination transaction with FasTrack Pharmaceuticals, Inc., whereby FasTrack became our wholly-owned subsidiary.

We are obligated to file certain interim and periodic reports including an annual report with audited financial statements. Our trading symbol is INNV. The financial statements included in this prospectus are for the combined entity including FasTrack Pharma.

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Prior Transactions 37

# **Manufacturing**

At the present time, we do not have any customers or backlog.

We intend to contract with third parties for the manufacture of our compounds for investigational purposes, for preclinical and clinical testing and for commercial sale of any FDA-approved products. All of our compounds are small molecules, generally constructed using industry standard processes and use readily accessible raw materials.

# **Regulatory Requirements**

On December 12, 2011, we filed a Report on Form 8-K describing and reporting the closing of the Agreement between North Horizon and FasTrack. The report was filed within four business days of the closing of the transaction. (See Item 5.01(a)(8) of Form 8-K.) Amendments to Rule 144 effective on February 15, 2008, limited the resale of most securities of a shell company until one year after the filing of the required information about FasTrack. These requirements may be perceived as limiting or eliminating the advantages of using reverse reorganizations or mergers of going public. In these transactions the management and shareholders of the acquired company become the controlling shareholders of the public company. Pursuant to applicable regulations a shell company may not use Form S-8 until 60 days after the company is no longer considered to be a shell company.

Amendments to Rule 144 effective on February 15, 2008 limited the tradeability of the issued and outstanding securities of a shell company, including shares issued in any transaction involving an acquisition of another business entity or prospect. Our shareholders are subject to these provisions.

Our shares are also considered penny stocks. Section 15g-2 of the regulations under the Exchange Act requires broker-dealers transacting trades in penny stocks to provide potential investors with a disclosure statement detailing the risks of investing in penny stocks and to have the investor sign a receipt of the disclosure statement before any transactions may occur in the investor s account. Also, broker-dealers must approve the account of an investor purchasing penny stocks. Our shares of common stock are classified as a penny stock.

# **Government Regulation**

The U.S. Food and Drug Administration ( *FDA* ) and other federal, state, local and foreign regulatory agencies impose substantial requirements upon the clinical development, approval, labeling, manufacture, marketing and distribution of drug products. These agencies regulate, among other things, research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, advertising and promotion of our product candidates. The regulatory approval process is generally lengthy and expensive, with no guarantee of a positive result. Moreover, failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, injunctive relief including partial or total suspension of production, or withdrawal of a product from the market.

The FDA regulates, among other things, the research, manufacture, promotion and distribution of drugs in the United States under the Federal Food, Drug and Cosmetic Act ( *FFDCA* ) and other statutes and implementing regulations. The process required by the FDA before prescription drug product candidates may be marketed in the United States generally involves the following:

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completion of extensive nonclinical laboratory tests, animal studies and formulation studies, all performed in accordance with the FDA s Good Laboratory Practice regulations;

submission to the FDA of an Investigational New Drug application ( *IND* ), which must become effective before human clinical trials may begin;

for some products, performance of adequate and well-controlled human clinical trials in accordance with the FDA s regulations, including Good Clinical Practices, to establish the safety and efficacy of the product candidate for each proposed indication;

submission to the FDA of a New Drug Application ( *NDA* );

satisfactory completion of an FDA preapproval inspection of the manufacturing facilities at which the product is produced to assess compliance with current Good Manufacturing Practice, or cGMP, regulations; and FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug. The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Nonclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals and other animal studies. The results of nonclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. Some nonclinical testing may continue even after an IND is submitted. The IND also includes one or more protocols for the initial clinical trial or trials and an investigator s brochure. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to the proposed clinical trials as outlined in the IND and places the clinical trial on a clinical hold. In such cases, the IND sponsor and the FDA must resolve any outstanding concerns or questions before any clinical trials can begin. Clinical trial holds also may be imposed at any time before or during studies due to safety concerns or non-compliance with regulatory requirements. An independent institutional review board, or IRB, at each of the clinical centers proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the consent form signed by the trial participants and must monitor the study until completed.

Our product pipeline is comprised of candidates in various stages of development. On the Rx side, to develop a product to Phase 2 based on the 505b(2) regulatory path would cost approximately \$4 million and take 18 months per candidate. On the OTC side, we estimate that the cost and process to register Apeaz with the FDA and build-out sufficient inventory for launch would cost approximately \$30,000 and take 3 to 6 months. See Clinical Trials and 505(b)(2) NDAs for further clarifications. No assurance can be given that the Company will be successful in any of its development or licensing efforts.

# **Clinical Trials**

Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified medical investigators according to approved protocols that detail the objectives of the study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor participant safety. Each protocol is submitted to the FDA as part of the IND.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap, or be combined.

Phase 1 clinical trials typically involve the initial introduction of the product candidate into healthy human volunteers. In Phase 1 clinical trials, the product candidate is typically tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.

Phase 2 clinical trials are conducted in a limited patient population to gather evidence about the efficacy of the product candidate for specific, targeted indications, to determine dosage tolerance and optimal dosage and to identify possible adverse effects and safety risks.

Phase 3 clinical trials are undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites. The size of Phase 3 clinical trials depends upon clinical and statistical considerations for the product candidate and disease, but sometimes can include several thousand patients. Phase 3 clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

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Clinical testing must satisfy extensive FDA regulations. Reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted for serious and unexpected adverse events. Success in early stage clinical trials does not assure success in later stage trials.

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The FDA, an IRB or our company may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk.

# **New Drug Applications**

Assuming successful completion of the required clinical trials, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA. An NDA also must contain extensive manufacturing information, as well as proposed labeling for the finished product. An NDA applicant must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP. The manufacturing process must be capable of consistently producing quality products within specifications approved by the FDA. The manufacturer must develop methods for testing the quality, purity and potency of the final product. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf life. Prior to approval, the FDA will conduct an inspection of the manufacturing facilities to assess compliance with cGMP.

The FDA reviews all NDAs submitted before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to review before the FDA accepts it for filing. After an application is filed, the FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers them carefully when making decisions. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA. If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require us to conduct Phase 4 testing which involves clinical trials designed to further assess a drug s safety and effectiveness after NDA approval, and may require surveillance programs to monitor the safety of approved products which have been commercialized. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety or efficacy questions arise after the product reaches the market.

# Section 505(b)(2) NDAs

There are two types of NDAs: the full NDA and the Section 505(b)(2) NDA. When possible, we intend to file Section 505(b)(2) NDAs that might, if accepted by the FDA, save time and expense in the development and testing of our product candidates. A full NDA is submitted under Section 505(b)(1) of the FFDCA, and must contain full reports of investigations conducted by the applicant to demonstrate the safety and effectiveness of the drug. A Section 505(b)(2) NDA may be submitted for a drug for which one or more of the investigations relied upon by the applicant were not conducted by or for the applicant and for which the applicant has no right of reference from the person by or for whom the investigations were conducted. A Section 505(b)(2) NDA may be submitted based in whole or in part on published literature or on the FDA s finding of safety and efficacy of one or more previously approved drugs, which are known as reference drugs. Thus, the filing of a Section 505(b)(2) NDA may result in approval of a drug based on fewer clinical or nonclinical studies than would be required under a full NDA. The number and size of studies that need to be conducted by the sponsor depends on the amount and quality of data pertaining to the reference drug that are publicly available, and on the similarity of and differences between the applicant s drug and the reference drug. In some cases, extensive, time-consuming, and costly clinical and nonclinical studies may still be required for approval

of a Section 505(b)(2) NDA.

Because we may develop new formulations of previously approved chemical entities, our drug approval strategy is to submit Section 505(b)(2) NDAs to the FDA. The FDA may not agree that our product candidates are approvable as Section 505(b)(2) NDAs. If the FDA determines that Section 505(b)(2) NDAs are not appropriate and that full NDAs are required for our product candidates, the time and financial resources required to obtain FDA approval for product candidates could substantially and materially increase,

and our products might be less likely to be approved. If the FDA requires full NDAs for product candidates, or requires more extensive testing and development for some other reason, our ability to compete with alternative products that arrive on the market more quickly than the product candidates would be adversely impacted.

### **Patent Protections**

We currently have one patent issued for Regia<sup>TM</sup> in Morocco and one issued in the U.S.A., and an application pending in Europe. We also have a series of patent applications pending in the U.S.A. and internationally for our SSAO technology platform.

An applicant submitting a Section 505(b)(2) NDA must certify to the FDA the patent status of the reference drug upon which the applicant relies in support of approval of its drug. With respect to every patent listed in the FDA s Orange Book, which is the FDA s list of approved drug products, as claiming the reference drug or an approved method of use of the reference drug, the Section 505(b)(2) applicant must certify that: (1) there is no patent information listed by the FDA for the reference drug; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date; (4) the listed patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the product in the Section 505(b)(2) NDA; or (5) if the patent is a use patent, that the applicant does not seek approval for a use claimed by the patent. If the applicant files a certification to the effect of clause (1), (2) or (5), FDA approval of the Section 505(b)(2) NDA may be made effective immediately upon successful FDA review of the application, in the absence of marketing exclusivity delays, which are discussed below. If the applicant files a certification to the effect of clause (3), the Section 505(b)(2) NDA approval may not be made effective until the expiration of the relevant patent and the expiration of any marketing exclusivity delays.

If the Section 505(b)(2) NDA applicant provides a certification to the effect of clause (4), referred to as a paragraph IV certification, the applicant also must send notice of the certification to the patent owner and the holder of the NDA for the reference drug. The filing of a patent infringement lawsuit within 45 days of the receipt of the notification may prevent the FDA from approving the Section 505(b)(2) NDA for 30 months from the date of the receipt of the notification unless the court determines that a longer or shorter period is appropriate because either party to the action failed to reasonably cooperate in expediting the action. However, the FDA may approve the Section 505(b)(2) NDA before the 30 months have expired if a court decides that the patent is invalid, unenforceable, or not infringed, or if a court enters a settlement order or consent decree stating the patent is invalid or not infringed.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years certain brand-name pharmaceutical companies and others have objected to the FDA s interpretation of Section 505(b)(2). If the FDA s interpretation of Section 505(b)(2) is successfully challenged in court, the FDA may be required to change its interpretation of Section 505(b)(2) which could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit. The pharmaceutical industry is highly competitive, and it is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. Moreover, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

# Marketing Exclusivity

Market exclusivity provisions under the FFDCA can delay the submission or the approval of Section 505(b)(2) NDAs, thereby delaying a Section 505(b)(2) product from entering the market. The FFDCA provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, or NCE, meaning that the FDA

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has not previously approved any other drug containing the same active moiety. This exclusivity prohibits the submission of a Section 505(b)(2) NDA for any drug product containing the active ingredient during the five-year exclusivity period. However, submission of a Section 505(b)(2) NDA that certifies that a listed patent is invalid, unenforceable, or will not be infringed, as discussed above, is permitted after four years, but if a patent infringement lawsuit is brought within 45 days after such certification, FDA approval of the Section 505(b)(2) NDA may automatically be stayed until 7½ years after the NCE approval date. The FFDCA also provides three years of marketing exclusivity for the approval of

new and supplemental NDAs for product changes, including, among other things, new indications, dosage forms, routes of administration or strengths of an existing drug, or for a new use, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by FDA to be essential to the approval of the application. Five-year and three-year exclusivity will not delay the submission or approval of another full NDA; however, as discussed above, an applicant submitting a full NDA under Section 505(b)(1) would be required to conduct or obtain a right of reference to all of the preclinical and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Other types of exclusivity in the United States include orphan drug exclusivity and pediatric exclusivity. The FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Seven-year orphan drug exclusivity is available to a product that has orphan drug designation and that receives the first FDA approval for the indication for which the drug has such designation. Orphan drug exclusivity prevents approval of another application for the same drug for the same orphan indication, for a period of seven years, regardless of whether the application is a full NDA or a Section 505(b)(2) NDA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Pediatric exclusivity, if granted, provides an additional six months to an existing exclusivity or statutory delay in approval resulting from a patent certification. This six-month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued Written Request for such a study.

Section 505(b)(2) NDAs are similar to full NDAs filed under Section 505(b)(1) in that they are entitled to any of these forms of exclusivity if they meet the qualifying criteria. They also are entitled to the patent protections described above, based on patents that are listed in the FDA s Orange Book in the same manner as patents claiming drugs and uses approved for NDAs submitted as full NDAs.

# **Other Regulatory Requirements**

Maintaining substantial compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Drug manufacturers are required to register their establishments with the FDA and certain state agencies, and after approval, the FDA and these state agencies conduct periodic unannounced inspections to ensure continued compliance with ongoing regulatory requirements, including cGMPs. In addition, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. The FDA may require post-approval testing and surveillance programs to monitor safety and the effectiveness of approved products that have been commercialized. Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including:

meeting record-keeping requirements;
reporting of adverse experiences with the drug;
providing the FDA with updated safety and efficacy information;
reporting on advertisements and promotional labeling;
drug sampling and distribution requirements; and
complying with electronic record and signature requirements.

In addition, the FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. There are numerous regulations and policies that govern various means for disseminating information to health-care professionals as well as consumers, including to industry

sponsored scientific and educational activities, information provided to the media and information provided over the Internet. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

The FDA has very broad enforcement authority and the failure to comply with applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us or on the manufacturers and distributors of our approved products, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions, restitution, and disgorgement of profits, recall or seizure of products, total or partial suspension of production or distribution, withdrawal of approvals, refusal to approve pending applications, and criminal prosecution resulting in fines and incarceration. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label or unapproved uses may be subject to significant liability. In addition, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

# Food and Drug Administration Amendments Act of 2007

In September 2007, the Food and Drug Administration Amendments Act of 2007, or FDAAA, became law. This legislation grants significant new powers to the FDA, many of which are aimed at improving drug safety and assuring the safety of drug products after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information, and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. In addition, the new law significantly expands the federal government sclinical trial registry and results databank and creates new restrictions on the advertising and promotion of drug products. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties.

The FDA has not yet implemented many of the provisions of the FDAAA, so we cannot predict the impact of the new legislation on the pharmaceutical industry or our business. However, the requirements and changes imposed by the FDAAA may make it more difficult, and more costly, to obtain and maintain approval for new pharmaceutical products, or to produce, market and distribute existing products. In addition, the FDA s regulations, policies and guidance are often revised or reinterpreted by the agency or the courts in ways that may significantly affect our business and our products. It is impossible to predict whether additional legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, or what the impact of such changes, if any, may be.

Our business activities are subject to general governmental regulations. In addition, we are obligated to file periodic reports as required by the Exchange Act. We are deemed to be a smaller reporting company as defined in Regulation S-K. The SEC adopted rules which phased out filings under Regulation SB and smaller reporting companies are now required to file reports under the provisions of Regulation S-K. A Smaller Reporting Company is defined as a company which has a public float held by non-affiliates of \$75 million or less. Companies without a calculable equity float will qualify if their revenues were below \$50 million in the previous year.

# **Principal Products or Services**

See previous discussion on Our Business.

# Competition

We are engaged in a highly competitive business. We expect competition from numerous companies, including large international enterprises, and others entering the market with product similar to ours. Most of these companies have superior research and development, manufacturing, patent, legal marketing, financial, technological, personnel and managerial resources. Acquisition of competing companies by large pharmaceutical or healthcare companies could further enhance our competitors' financial, marketing and other resources. Competitors may complete clinical trials, obtain regulatory approvals and commence commercial sales of their products before we could enjoy significant competitive advantages. Products developed by our competitors may be safer and more effective as compared to our products under development.

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# **Facilities, Equipment and Employees**

We currently have no corporate office. Our one employee operates from her private residence.

# **Effect of Governmental Regulations on Our Business**

See previous discussion on regulatory requirements.

We are a smaller reporting company subject to reporting requirements of the SEC. We are subject to the provisions of the Sarbanes-Oxley Act of 2002. It created an accounting oversight board to oversee the conduct of auditors of public companies and to ensure auditor independence. This Act imposes the obligations on management for financial reporting and quality financial disclosures, and to expose possible conflicts of interest. It also creates guidelines for audit committees, oversight of the audits performed by public auditing firms, and requires management to make assessments of internal controls procedures and other matters. Compliance with the provisions of this statute will increase our legal and accounting costs.

We are subject to the rules regarding proxy solicitations including the provisions of Regulation 14A. We may be required to provide to shareholders an information statement complying with the provisions of Schedules 14A or 14C.

Jobs Act disclosures

# Research and Development Costs During the Past Two Years

During the years ended December 31, 2011 and 2010 the Company has incurred research and development costs totaling \$58,960 and \$0, respectively.

# **Cost and Effects of Compliance with Environmental Laws**

Currently we are not subject to material environmental laws, rules, or regulations that would have an adverse impact on our business operations or financial conditions.

### Inflation

We believe that inflation has little impact on our business affairs.

# **Employees**

We currently have one employee who serves as our President and Chief Executive Officer. Our one employee is not represented by a labor union, and has good relations with the Company. See *Management* for biographical information on our management team and directors. Subject to the availability of financing our intention is to expand our staff to five employees within 12 months in order to implement our growth strategy.

# **Reports**

You may locate reports on the SEC's Internet site at *www.sec.gov*. The SEC's telephone number is 202-551-8090. Materials about us are available through the SEC Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549.

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# MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Included in this memorandum are financial statements, audited and unaudited, of Innovus Pharma.

The Company s unaudited financial statements for the three months and six months ended June 30, 2012 and 2011, and the audited financial statements for the years ended December 31, 2011, and 2010, are included among the financial statements in this memorandum. The Company has not paid any dividends.

Innovus Pharma has not had changes in or disagreements with its accountants on any accounting or financial matters. The following is the Company s management s discussion and analysis of financial condition and results of operations.

At June 30, 2012, the Company had \$105,726 in cash as compared to \$25,014 at December 31, 2011. On January 13, 2012, the Board of Directors authorized to issue a total of \$174,668 in convertible promissory notes (the January Notes) to six individuals. One January Note for \$74,668 was issued to an accredited investor to settle liabilities assumed from North Horizon and therefore this did not result in any cash inflow for us. Five January Notes for a total of \$100,000 in a new cash infusion were issued to five individuals, three of who are members of the Company's Board of Directors. The January Notes bear an annual interest rate of 8% and are payable in cash at the earlier of January 13, 2013, or when the Company completes a financing of a minimum of \$4 million (the Financing). The holders of the January Notes have the option to convert their principal and interest accrued into the Company s securities (New Financing Securities) that will be issued to the investors in a future financing. In the event the Company defaults on repayment, or if the Company fails to complete a financing within one year of the note date, the annual interest rate would increase to 13% and the holders of the January Notes would have the option to convert the note to the Company s common stock at \$0.05 per share.

On June 26, 2012 the Company issued 134,000 shares of common stock to an unrelated investor at \$0.75 per share for cash proceeds of \$100,500. Also on June 26, 2012 the Company and an unrelated noteholder reached a settlement on outstanding balance of \$12,000, plus accrued interest of \$435, of the convertible debenture whereas the fair value of the 16,580 shares of common stock issued approximated the carrying value of the outstanding convertible debenture at time of settlement. Accordingly, no gain or loss resulted from the settlement.

For the three months ended June 30, 2012 and 2011, the Company earned no revenues, and consequently, had no cost of sales. Gross profits for the first three months in 2012 and 2011 were \$0. Operating expenses for the three months ended June 30, 2012 and 2011 totaled \$49,849 and \$50,994, respectively, marking a \$1,145 decrease. This minor decrease was primarily the result of minor decreases in professional fees as a result of the completion of the reverse merger transaction in December 2011 and the filing of our first Form 10K in March 2012. The Company recognized interest expense of \$4,472 and \$4,730 for the three months ended June 30, 2012 and 2011, respectively, resulting in a change of \$(258). This change is primarily the result of decreased level of debt during 2012 compared to 2011. The Company recognized net losses in the amount of \$54,321 and \$55,724, for the three-month periods ended June 30, 2012 and 2011, respectively. This decreased net loss results primarily from minor decreases in operating expenses and interest expense.

For the six months ended June 30, 2012 and 2011, the Company earned no revenues, and consequently, no cost of sales. Operating expenses for the six months ended June 30, 2012 and 2011 totaled \$106,126 and \$71,200,

respectively, marking a \$34,926 increase. This increase was primarily the result of increases in professional fees as a result of the completion of the reverse merger transaction in December 2011 and the filing of our first Form 10K in March 2012. The Company recognized interest expense of \$8,455 and \$9,050 for the six months ended June 30, 2012 and 2011, respectively, resulting in a change of \$(595). This change is primarily the result of decreased level of debt during 2012 compared to 2011. The Company recognized net losses in the amount of \$114,581 and \$80,250, for the six-month periods ended June 30, 2012 and 2011, respectively. This increased net loss results primarily from increases in operating expenses and interest expense.

For the years ended December 31, 2011 and 2010, the Company earned no revenues, and consequently, had no cost of sales. Gross profits for the 2011 and 2010 years was \$0. The operating expenses for the years

ended December 31, 2011 and 2010 totaled \$2,188,535 and \$53,601, respectively, marking a \$2,134,934 increase. This increase was primarily the result of increases in research and development costs (\$58,960), professional fees (\$131,276), and compensation expense (\$1,954,029), including fair value of warrants issued to an investment banker of \$1,904,865. The Company recognized interest expense of \$67,717 and \$16,322 for the years ended December 31, 2011 and 2010, respectively, resulting in a change of \$51,395. This change is primarily the result of increased level of debt during 2011 compared to 2010 and \$48,920 discount recorded on the conversion of convertible notes. The Company recognized net losses in the amount of \$2,256,252 and \$69,923, for the years ended December 31, 2011 and 2010, respectively. This increased net loss results primarily from increased operating expenses and interest expense.

The Company has experienced net losses and negative cash flows from operations each year since its inception. Through June 30, 2012, the Company had an accumulated deficit of approximately \$2,865,004. The Company s operations have been financed through advances from officers and directors and related parties. The Company has not yet had sufficient funds to significantly develop its technologies. As a result of its losses to date, expected losses in the future, limited capital resources and accumulated deficit, there is substantial doubt as to the Company s ability to continue as a going concern. The Company s continuation is based on the Company s ability to generate or obtain sufficient cash to meet our obligations on a timely basis and ultimately to attain profitable operations. The Company anticipates that it will continue to incur significant losses at least until successful commercialization of one or more of its products. In light of management s efforts, there are no assurances that the Company will be successful in this or any of its endeavors or become financially viable and continue as a going concern.

# **Related Party Transactions**

On March 4, 2011, FasTrack issued a promissory note to Baltimore Medical and Surgical Associates, PA, an entity controlled by Dr. Ziad Mirza, a director of FasTrack. On April 5, 2011, FasTrack paid the note s principal and accrued interest.

On January 13, 2012, the Board of Directors authorized a total of \$174,668 in promissory notes (the *January Notes*) to six individuals. One January Note for \$74,668 was issued to one accredited investor for the liabilities assumed from North Horizon, Inc. Five January Notes for a total of \$100,000 were issued to five individuals for cash consideration of \$100,000, three of whom are members of the Company's Board of Directors. The January Notes bear an annual interest rate of 8% and payable in cash at the earlier of January 13, 2012, or when the Company completes a financing of a minimum of \$4 million (the *Financing*). The holders of the January Notes have the right to convert their principal and interest accrued into the Company's securities at the same terms as the investors in the Financing. In the event the Company defaults on repayment, the annual interest rate would increase to 13% and the holders of the January Notes would have the right to convert at \$0.05 per share.

In January 2010, FasTrack s Board of Directors approved \$7,000 in payment to Dr. Bassam Damaj, our largest shareholder and the CEO of Apricus Bio. The payment was for overhead expenses. The agreement included a provision that if FasTrack could not pay cash, Dr. Damaj would receive 1% of Fastrack s outstanding equity based on its outstanding shares as of January 15, 2011. On February 7, 2011, FasTrack issued 134,364shares (as converted post combination) of common stock to Dr. Damaj to satisfy the obligation.

In January 2010, the Sorrento Board of Directors approved a payment of \$7,000 to Dr. Damaj for 2010 overhead expenses. The agreement had a similar provision as the FasTrack agreement. Sorrento paid cash of \$7,000 to satisfy the obligation.

From October 2009 to 2011, directors and officers of the Company have advanced cash or incurred FasTrack s expenses. The amounts varied from \$600 to \$5,000. Substantially all such advances have been repaid.

Since October 2009 FasTrack and Sorrento entered into agreements with others that are deemed to be related parties. In October 2009 FasTrack acquired the right to PrevOnco from Bio-Quant for \$276,020 paid for by 13,372,384 shares of FasTrack common stock (as converted post combination) and the issuance of a promissory note in the amount of \$250,000. In October 2009 Sorrento purchased from Bio-Quant the rights of

Apeaz and Regia for a purchase price of \$120,858 paid for with 4,379 shares of Sorrento s common stock valued at \$11,000 and a promissory note.

In March 2010, FasTrack entered into an Agreement with NexMed in which FasTrack sold the development rights of PrevOnco<sup>TM</sup> to NexMed for cancellation of \$204,896 of the FasTrack Promissory Note and a right to 50% of the net proceeds, defined as gross proceeds less 115% of the aggregate development expenses incurred by NexMed.

In March 2011, FasTrack acquired Sorrento s over-the counter products. FasTrack assumed Sorrento s liabilities in the amount of \$142,808.

Because the three foregoing transactions are considered transaction with entities under common control, they have been recorded at historical carrying value (nil) and as equity transactions deemed contributions or distribution.

In April 2011 FasTrack entered into an Agreement with Apricus Bio described herein.

The notes and accrued interest at the date of conversion (as described below) to Apricus Bio aggregated to \$489,061, bore per annum interest of 4.25% and were due on April 4, 2013. These notes were secured by a first priority security interest in the assets of the Company. The notes are convertible upon the happening of either financing of more than \$2,000,000 or a merger or acquisition transaction prior to the maturity date. Any outstanding amount will convert on the date of closing of the financing or the merger or acquisition at a price per share equal to ninety per cent (90%) of the price of the shares sold in the financing or exchange in the merger or acquisition. On December 22, 2011, the notes were convertible into 135,888 shares of the Company s common stock, pursuant to the terms of the note agreement. The shares which have trading restrictions until December 12, 2012, were physically delivered to Apricus Bio in March 2012.

In the past, the principal shareholder of North Horizon, Inc., who was also one of its directors and its president advanced funds to pay in the amount of \$26,601 for expenses North Horizon incurred in 2011.

# Off-balance Sheet Arrangements

We have no off-balance sheet arrangements.

# **Recent Accounting Pronouncements**

See Footnote 2 to our consolidated financial statements for the periods ended December 31, 2011 and 2010. The adoption of recently implemented accounting rules and policies did not have any impact on the Company's financial position, results of operations or cash flows.

# MANAGEMENT AND BOARD OF DIRECTORS

The Company's directors are Vivian Liu, Dr. Ziad Mirza, and Dr. Henry Esber. The following is biographical information about our directors. The Company anticipates that in the near term new directors may be selected and appointed.

Vivian Liu, 51, is a director, President and Chief Executive Officer. Ms. Liu became President and Chief Executive Officer in January 2011. In 1995 Ms. Liu co-founded NexMed, Inc., which in 2010 was renamed to Apricus

BioSciences, Inc. Apricus Bio trades on NASDAQ with the symbol APRI. Ms. Liu was NexMed s President and Chief Executive Officer from 2007 to 2009. Prior to her appointment as President, Ms. Liu served in several executive capacities, including Executive Vice President, Chief Operating Officer, Chief Financial Officer, and Vice President of Corporate Affairs. She was appointed as a director of NexMed in 2007 and served as Chairman of the Board from 2009 to 2010. Ms. Liu has an M.P.A. from the University of Southern California, and has a B.A. from the University of California, Berkeley.

We agreed with Ms. Liu that she would not be paid a salary until the Company raised at least \$500,000 in cash, after which she would commence to receive an annual salary of \$150,000. Ms. Liu received 833,668 shares of the Company's common stock upon the closing of the reverse merger. The stock granted to Ms. Liu contains anti-dilution provision. Ms. Liu would be issued additional shares in such a way, that she would retain 2%, 4% and 6% ownership of the Company at December 31, 2011, 2012 and 2013, respectively, assuming continuous and uninterrupted employment with the Company. No additional shares were issued or

issuable through December 31, 2011 as her ownership percentage exceeds 2%. If additional shares are to be issued, a compensatory charge will be recognized.

Henry Esber, Ph.D, 73, has served as a Director of FasTrack since January 2011. In 2000 Dr. Esber co-founded Bio-Quant, Inc., the largest pre-clinical discovery contract research organization in San Diego, California. From 2000 to 2010 he served as its Senior Vice President and Chief Business Development Officer. Dr. Esber has more than thirty-five years experience in the pharmaceutical service industry. Dr. Esber currently serves on the Board of Directors of Apricus Bio and several private pharmaceutical companies. In the event that a potential conflict of interest arises between FasTrack and Apricus Bio, Mr. Esber will abstain from participating in the decision involving the conflict.

Ziad Mirza, M.D., 49, is a director of FasTrack and has served as Chairman of the Board of Directors since March 2010. He also served as FasTrack's Acting Chief Executive Officer from March 2010 to December 2010. He is the President and co-founder of Baltimore Medical and Surgical Associates. He is a Certified Medical Director of long term care through the American Medical Directors Association. He is as well a Certified Physician Executive from the American College of Physician Executives. He consults for pharmaceutical companies on clinical trial design. He has a medical degree from the American University of Beirut and completed his residency at Good Samaritan Hospital in Baltimore. He received an MBA from the University of Massachusetts. Dr. Mirza is a relative of Dr. Damaj, our largest shareholder.

In the near term the Company's intends to appoint three new independent directors, with at least one of the new appointees being an audit committee financial expert as defined in Item 407(d)(5) of the SEC's Regulation S-K.

# **Legal Proceedings**

The Company is not involved in any legal proceedings.

# **Recent Sales of Unregistered Shares**

On June 26, 2012 the Company issued 134,000 shares of common stock to an unrelated investor at \$0.75 per share for cash proceeds of \$100,500. Also on June 26, 2012 the Company and an unrelated noteholder reached a settlement on outstanding balance of \$12,000, plus accrued interest of \$435, of the convertible debenture whereas the fair value of the 16,580 shares of common stock issued approximated the carrying value of the outstanding convertible debenture at time of settlement. Accordingly, no gain or loss resulted from the settlement.

# **Changes and Disagreements with Accountants**

Neither the Company nor FasTrack has had any disagreements with its accountants on accounting and financial disclosures.

# STOCK OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Stock ownership of Officers and Directors and Major Shareholders (5% or more). The number of shares owned

includes direct and beneficial ownership. The percentages are based on 16,714,143 shares of common stock outstanding on a fully-diluted basis.

Name	Number of Shares Owned Beneficially	Percentage of Company		
Vivian Liu	833,669	5.02	Officer and Director (1	1)
Henry Esber	2,252,126	13.5	Director	1)
Ziad Mirza	403,346	2.4	Director	1)
Wallace Boyack	840,579	5.02		
Ramon Jadra	980,147	5.91		
Bassam Damaj & Family <sup>(2)</sup>	4,649,301	28		

<sup>(1)</sup> The officers and directors own 3,489,141 shares of common stock which is 21% of the issued and outstanding shares.

Apricus Bio is now one of our shareholders through the conversion of a convertible promissory note which converted into 135,888 shares of our Common Stock on December 21, 2011. The Apricus Bio shares are included in the shares held beneficially by Bassam Damaj because he currently serves as a Director, President & Chief Executive Officer of Apricus Bio.

# Change in Status No Longer a Shell Company

Previously we were designated as a shell company as that term is defined in Rule 12b-2 promulgated under the Securities Exchange Act of 1934. As a result of the Closing of the reverse merger with FasTrack, FasTrack became our subsidiary and main operating business. FasTrack has assets which it is seeking to develop and pursue. With an operating business we are no longer a shell company.

More information about the Company is available because we file annual, quarterly, and current reports and other information with the SEC that states additional information about our company. These materials are available at the public reference facilities of the SEC s Washington, D.C. office, at 100 F Street, NE, Washington, D.C. 20549 and on the SEC Internet site at <a href="http://www.sec.gov">http://www.sec.gov</a>.

## **Innovus Pharma Financial Statements**

The audited financial statements of Innovus Pharmaceuticals, Inc., as of December 31, 2011, and December 31, 2010, are attached. Unaudited financial statements as of June 30, 2012 and 2011, are attached.

# **DESCRIPTION OF SECURITIES**

# **Common Stock**

We are authorized to issue up to 150,000,000 shares of Common Stock, par value \$0.001 per share. As of the date of this Memorandum, there are approximately 16,333,670 shares of Common Stock issued and outstanding. The outstanding shares of Common Stock are validly issued, fully paid and nonassessable.

Holders of Common Stock are entitled to one vote for each share on all matters submitted to a stockholder vote. Holders of Common Stock do not have cumulative voting rights. Therefore, holders of a majority of the shares of Common Stock voting for the election of directors can elect all of the directors. Holders of Common Stock representing a majority of the voting power of the Company s capital stock issued, outstanding and entitled to vote, represented in person or by proxy, are necessary to constitute a quorum at any meeting of stockholders. A vote by the holders of a majority of the Company s outstanding shares is required to effectuate certain fundamental corporate changes such as liquidation, merger or an amendment to the Company s certificate of incorporation.

Holders of Common Stock are entitled to share in all dividends that our Board of Directors, in its discretion, declares from legally available funds. In the event of a liquidation, dissolution or winding up, each outstanding share entitles its holder to participate pro rata in all assets that remain after payment of liabilities and after providing for each class of stock, if any, having preference over the Common Stock. The Common Stock has no pre-emptive, subscription or conversion rights and there are no redemption provisions applicable to the Common Stock.

# DISCLOSURES OF COMMISSION'S POSITION ON INDEMNIFACTION FOR SECURITIES ACT LIABILITIES

Our bylaws provide that directors, officers and any person who acted at our request will be indemnified to the fullest extent authorized by the Nevada Revised Statutes against all expenses and liabilities reasonably incurred in connection with services for us or on our behalf if:

such person acted in good faith,

acted in an manner he or she reasonably believed to be in or not opposed to the best interest of the corporation and had no reason to believe in a criminal matter that the conduct was unlawful.

Insofar as indemnification for liabilities arising under the Securities Act might be permitted to directors, officers or persons under the provisions described above, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

# **LEGAL MATTERS**

Wallace T. Boyack, P.C. at 2290 East 4500 South, Suite 130, Salt Lake City, UT 84117, telephone (801) 278-9925, has acted as our legal counsel.

# **EXPERTS**

The financial statements of the Company as of December 31, 2011 and 2010, and for each of the two years in the period ended December 31, 2011 and the period from inception (October 31, 2008) through December 31, 2011 then ended included in this Prospectus have been so included in reliance on the report of EisnerAmper LLP (which contains an explanatory paragraph relating to the Company s ability to continue as a going concern as described in Note 2 to the financial statements), an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

# INTEREST OF NAMED EXPERTS AND COUNSEL

No expert or counsel was hired on a contingency basis. The auditing firm will not receive a direct or indirect interest in the company, nor will it act, or has acted as a promoter, underwriter, voting trustee, director, officer or employee of the company. Mr. Boyack is a shareholder owning 840,579 shares of common stock and prior to December 7, 2011, served as an officer and director of North Horizon for several years (prior to combination with FasTrack).